Australian Government

Department of Health, Disability and Ageing

PBS

Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 November 2026

Fees, Patient Contributions and Safety Net Thresholds

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

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

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

Summary of Changes

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

Prescriber Bag

Additions

Addition – Item

13828T **SALBUTAMOL**, salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules *(PMS-SALBUTAMOL (Canada))*

Advance Notices

1 January 2027

Deletion – Brand

3486L *BenPen, SZ* – **BENZYLPENICILLIN**, benzylpenicillin 600 mg injection, 1 vial

General Pharmaceutical Benefits

Additions

Addition – Item

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Addition – Brand

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13764K *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
14221L *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
14234E *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
14242N *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
14272E *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
14973C *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
15031D *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
15038L *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
15146E *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
15153M *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
15159W *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
12360M *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device
12374G *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device
12419P *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device
12426B *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device
12447D *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device
12448E *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device
12449F *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device
12450G *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device
14587R *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device
1354G *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 20 mg tablet, 60
9125G *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 20 mg tablet, 60
12869H *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 20 mg tablet, 60
1381Q *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 50 mg tablet, 60
9126H *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 50 mg tablet, 60
12843Y *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 50 mg tablet, 60
1415L *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 70 mg tablet, 60
9127J *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 70 mg tablet, 60
12890K *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 70 mg tablet, 60
1416M *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 100 mg tablet, 30
9343R *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 100 mg tablet, 30
12889J *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 100 mg tablet, 30
8879H *Eplerenone Viatris, AL* – **EPLERENONE**, eplerenone 25 mg tablet, 30
13590G *Eplerenone Viatris, AL* – **EPLERENONE**, eplerenone 25 mg tablet, 30
8757X *Ezetimibe Viatris, MQ* – **EZETIMIBE**, ezetimibe 10 mg tablet, 30
13440J *Ezetimibe Viatris, MQ* – **EZETIMIBE**, ezetimibe 10 mg tablet, 30
3439B *Diaformin Viatris XR, VY* – **METFORMIN**, metformin hydrochloride 1 g modified release tablet, 60
13847T *Diaformin Viatris XR, VY* – **METFORMIN**, metformin hydrochloride 1 g modified release tablet, 60
1692C *Fudantin, NB* – **NITROFURANTOIN**, nitrofurantoin 50 mg capsule, 30
1693D *Fudantin, NB* – **NITROFURANTOIN**, nitrofurantoin 100 mg capsule, 30
8224W *Ondansetron VTRS, AF* – **ONDANSETRON**, ondansetron 4 mg tablet, 4
12192Q *Rivaroxaban Sandoz, SZ* – **RIVAROXABAN**, rivaroxaban 2.5 mg tablet, 60
12197Y *Rivaroxaban Sandoz, SZ* – **RIVAROXABAN**, rivaroxaban 2.5 mg tablet, 60
13366L *Rivaroxaban Sandoz, SZ* – **RIVAROXABAN**, rivaroxaban 2.5 mg tablet, 60

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Addition – Equivalence Indicator

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

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

Addition – Note

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

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

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

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

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

Deletions

Deletion – Item

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

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

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

Deletion – Brand

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

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

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

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

Deletion – Note

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

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

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

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

Deletion – Restriction

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

Supply Only

Supply Only – Period Commencing

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

Supply Only – Period Ending

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

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

Advance Notices

1 December 2026

Deletion – Item

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Deletion – Brand

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 January 2027

Deletion – Item

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

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

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

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

Deletion – Brand

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

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

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

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

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

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

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

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

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

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

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

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

1 February 2027

Deletion – Brand

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

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

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

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

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

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

15556R **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15585G **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15597X **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15622F **CICLOSPORIN**, ciclosporin 10 mg capsule, 60 *(Neoral 10)*

15666M **CICLOSPORIN**, ciclosporin 25 mg capsule, 30 *(APO-Ciclosporin, CICLOSPORIN-WGR, Neoral 25)*

15634W **CICLOSPORIN**, ciclosporin 50 mg capsule, 30 *(APO-Ciclosporin, CICLOSPORIN-WGR, Neoral 50)*

15663J **CICLOSPORIN**, ciclosporin 100 mg capsule, 30 *(APO-Ciclosporin, CICLOSPORIN-WGR, Neoral 100)*

15623G **CICLOSPORIN**, ciclosporin 100 mg/mL oral liquid, 50 mL *(Neoral)*

15620D **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 50 mg + tezacaftor 25 mg + ivacaftor 37.5 mg tablet [56] (&) ivacaftor 75 mg tablet [28], 84 *(Trikafta)*

15656B **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 80 mg + tezacaftor 40 mg + ivacaftor 60 mg granules [28] (&) ivacaftor 59.5 mg granules [28], 56 *(Trikafta)*

15646L **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84 *(Trikafta)*

15671T **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg granules [28] (&) ivacaftor 75 mg granules [28], 56 *(Trikafta)*

15613R **IVACAFTOR**, ivacaftor 25 mg granules, 56 sachets *(Kalydeco)*

15614T **IVACAFTOR**, ivacaftor 25 mg granules, 56 sachets *(Kalydeco)*

15662H **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

15680G **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

15650Q **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

15660F **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

15621E **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

15631Q **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

15678E **LANREOTIDE**, lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

15608L **LANREOTIDE**, lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

15637B **LANREOTIDE**, lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

15643H **LUMACAFTOR + IVACAFTOR**, lumacaftor 75 mg + ivacaftor 94 mg granules, 56 sachets *(Orkambi)*

15633T **LUMACAFTOR + IVACAFTOR**, lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets *(Orkambi)*

15676C **LUMACAFTOR + IVACAFTOR**, lumacaftor 100 mg + ivacaftor 125 mg tablet, 112 *(Orkambi)*

15664K **LUMACAFTOR + IVACAFTOR**, lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets *(Orkambi)*

15653W **LUMACAFTOR + IVACAFTOR**, lumacaftor 200 mg + ivacaftor 125 mg tablet, 112 *(Orkambi)*

15673X **MYCOPHENOLATE**, mycophenolate 180 mg enteric tablet, 120 *(Mycophenolic Acid ARX, Myfortic)*

15674Y **MYCOPHENOLATE**, mycophenolate 360 mg enteric tablet, 120 *(Mycophenolic Acid ARX, MYCOTEX, Myfortic)*

15628M **OCTREOTIDE**, octreotide 50 microgram/mL injection, 5 x 1 mL ampoules *(Octreotide (SUN), Octreotide GH, Sandostatin 0.05)*

15610N **OCTREOTIDE**, octreotide 100 microgram/mL injection, 5 x 1 mL ampoules *(Octreotide (SUN), Octreotide GH, Sandostatin 0.1)*

15648N **OCTREOTIDE**, octreotide 500 microgram/mL injection, 5 x 1 mL ampoules *(Octreotide (SUN), Octreotide GH, Sandostatin 0.5)*

15629N **OCTREOTIDE**, octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

15649P **OCTREOTIDE**, octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

15639D **OCTREOTIDE**, octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

15568J **TEPROTUMUMAB**, Teprotumumab 500 mg injection, 1 vial *(Tepezza)*

15605H **TEPROTUMUMAB**, Teprotumumab 500 mg injection, 1 vial *(Tepezza)*

15606J **TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56 *(Symdeko)*

15635X **TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56 *(Symdeko)*

Addition – Brand

12335F *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13229G *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

15142Y *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

11496C *Deferasirox FCT MSN, VM* – **DEFERASIROX**, deferasirox 360 mg tablet, 30

11511W *Deferasirox FCT MSN, VM* – **DEFERASIROX**, deferasirox 360 mg tablet, 30

11547R *Deferasirox FCT MSN, VM* – **DEFERASIROX**, deferasirox 360 mg tablet, 30

9620H *Sevelamer Waymade, IX* – **SEVELAMER**, sevelamer hydrochloride 800 mg tablet, 180

Deletions

Deletion – Restriction

13266F **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 50 mg + tezacaftor 25 mg + ivacaftor 37.5 mg tablet [56] (&) ivacaftor 75 mg tablet [28], 84 *(Trikafta)*

14279M **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 80 mg + tezacaftor 40 mg + ivacaftor 60 mg granules [28] (&) ivacaftor 59.5 mg granules [28], 56 *(Trikafta)*

12938Y **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84 *(Trikafta)*

14147N **IVACAFTOR**, ivacaftor 25 mg granules, 56 sachets *(Kalydeco)*

14165M **IVACAFTOR**, ivacaftor 25 mg granules, 56 sachets *(Kalydeco)*

11097C **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

14158E **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

11109Q **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

14157D **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

10175M **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

14169R **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

6423C **LANREOTIDE**, lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

6424D **LANREOTIDE**, lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

6425E **LANREOTIDE**, lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

13795C **LUMACAFTOR + IVACAFTOR**, lumacaftor 75 mg + ivacaftor 94 mg granules, 56 sachets *(Orkambi)*

11464J	**LUMACAFTOR + IVACAFTOR**, lumacaftor 100 mg + ivacaftor 125 mg tablet, 112 *(Orkambi)*
11841F	**LUMACAFTOR + IVACAFTOR**, lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets *(Orkambi)*
11848N	**LUMACAFTOR + IVACAFTOR**, lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets *(Orkambi)*
11463H	**LUMACAFTOR + IVACAFTOR**, lumacaftor 200 mg + ivacaftor 125 mg tablet, 112 *(Orkambi)*
6369F	**MYCOPHENOLATE**, mycophenolate 180 mg enteric tablet, 120 *(Mycophenolic Acid ARX, Myfortic)*
6370G	**MYCOPHENOLATE**, mycophenolate 360 mg enteric tablet, 120 *(Mycophenolic Acid ARX, MYCOTEX, Myfortic)*
6227R	**OCTREOTIDE**, octreotide 50 microgram/mL injection, 5 x 1 mL ampoules *(Octreotide (SUN), Octreotide GH, Sandostatin 0.05)*
6228T	**OCTREOTIDE**, octreotide 100 microgram/mL injection, 5 x 1 mL ampoules *(Octreotide (SUN), Octreotide GH, Sandostatin 0.1)*
6229W	**OCTREOTIDE**, octreotide 500 microgram/mL injection, 5 x 1 mL ampoules *(Octreotide (SUN), Octreotide GH, Sandostatin 0.5)*
10566D	**OCTREOTIDE**, octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*
10549F	**OCTREOTIDE**, octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*
10558Q	**OCTREOTIDE**, octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*
11833T	**TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56 *(Symdeko)*
11834W	**TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56 *(Symdeko)*

Alterations

Alteration – Authorised Prescriber

		From	*To*
6109M	**CICLOSPORIN**, ciclosporin 50 mg/mL injection, 10 x 1 mL ampoules *(Sandimmun)*	M	M,N
11545P	**DEFERASIROX**, deferasirox 90 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
11548T	**DEFERASIROX**, deferasirox 90 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
11558H	**DEFERASIROX**, deferasirox 90 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
6499C	**DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Deferasirox Juno)*	M	M,N
11236J	**DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Deferasirox Juno)*	M	M,N
11241P	**DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Deferasirox Juno)*	M	M,N
11510T	**DEFERASIROX**, deferasirox 180 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
11546Q	**DEFERASIROX**, deferasirox 180 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
11557G	**DEFERASIROX**, deferasirox 180 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
6500D	**DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Deferasirox Juno)*	M	M,N
11238L	**DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Deferasirox Juno)*	M	M,N
11244T	**DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Deferasirox Juno)*	M	M,N
11496C	**DEFERASIROX**, deferasirox 360 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
11511W	**DEFERASIROX**, deferasirox 360 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
11547R	**DEFERASIROX**, deferasirox 360 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N

		From	To
9600G	**DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Deferasirox Juno, Pharmacor Deferasirox)*	M	M,N
11232E	**DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Deferasirox Juno, Pharmacor Deferasirox)*	M	M,N
11243R	**DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Deferasirox Juno, Pharmacor Deferasirox)*	M	M,N
9638G	**DEFERIPRONE**, deferiprone 100 mg/mL oral liquid, 250 mL *(Ferriprox)*	M	M,N
6416Q	**DEFERIPRONE**, deferiprone 500 mg tablet, 100 *(Ferriprox)*	M	M,N
11724C	**DEFERIPRONE**, deferiprone 1 g tablet, 50 *(Ferriprox)*	M	M,N
6113R	**DESFERRIOXAMINE**, desferrioxamine mesilate 500 mg injection, 10 vials *(DBL Desferrioxamine Mesilate)*	M	M,N
6270B	**DESFERRIOXAMINE**, desferrioxamine mesilate 2 g injection, 1 vial *(DBL Desferrioxamine Mesilate)*	M	M,N
6120D	**DORNASE ALFA**, dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules *(Pulmozyme)*	M	M,N
6459Y	**EVEROLIMUS**, everolimus 250 microgram tablet, 60 *(Certican, Everocan)*	M	M,N
6460B	**EVEROLIMUS**, everolimus 500 microgram tablet, 60 *(Certican, Everocan)*	M	M,N
6461C	**EVEROLIMUS**, everolimus 750 microgram tablet, 60 *(Certican, Everocan)*	M	M,N
9582H	**EVEROLIMUS**, everolimus 1 mg tablet, 60 *(Certican, Everocan)*	M	M,N
5830W	**FILGRASTIM**, filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes *(Nivestim)*	M	M,N
2747N	**FILGRASTIM**, filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes *(Zarzio)*	M	M,N
6291D	**FILGRASTIM**, filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes *(Nivestim)*	M	M,N
2733W	**FILGRASTIM**, filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes *(Zarzio)*	M	M,N
6292E	**FILGRASTIM**, filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes *(Nivestim)*	M	M,N
11527Q	**LANREOTIDE**, lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*	M	M,N
2008Q	**MANNITOL**, mannitol 40 mg powder for inhalation, 280 capsules *(Bronchitol)*	M	M,N
11518F	**MIDOSTAURIN**, midostaurin 25 mg capsule, 112 *(Rydapt)*	M	M,N
6208R	**MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100 *(APO-Mycophenolate, Mycophenolate Sandoz, Pharmacor Mycophenolate 250)*	M	M,N
6209T	**MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50 *(ARX-MYCOPHENOLATE, Ceptolate, Mycophenolate GH, Mycophenolate Sandoz, Pharmacor Mycophenolate 500)*	M	M,N
6364Y	**MYCOPHENOLATE**, mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL *(CellCept, Pharmacor Mycophenolate)*	M	M,N
11894B	**OCTREOTIDE**, octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*	M	M,N
6363X	**PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe *(Pelgraz, Ziextenzo)*	M	M,N
9748C	**SIROLIMUS**, sirolimus 500 microgram tablet, 100 *(Rapamune)*	M	M,N
6436R	**SIROLIMUS**, sirolimus 1 mg tablet, 100 *(Rapamune)*	M	M,N
6437T	**SIROLIMUS**, sirolimus 1 mg/mL oral liquid, 60 mL *(Rapamune)*	M	M,N
6457W	**SIROLIMUS**, sirolimus 2 mg tablet, 100 *(Rapamune)*	M	M,N
6328C	**TACROLIMUS**, tacrolimus 500 microgram capsule, 100 *(Pacrolim, Pharmacor Tacrolimus 0.5, Prograf, Tacrograf, Tacrolimus Sandoz)*	M	M,N
9681M	**TACROLIMUS**, tacrolimus 500 microgram modified release capsule, 30 *(ADVAGRAF XL, Tacrolimus XR Sandoz)*	M	M,N
10875J	**TACROLIMUS**, tacrolimus 750 microgram capsule, 100 *(Tacrolimus Sandoz)*	M	M,N
6216E	**TACROLIMUS**, tacrolimus 1 mg capsule, 100 *(Pacrolim, Pharmacor Tacrolimus 1, Prograf, Tacrograf, Tacrolimus Sandoz)*	M	M,N
9682N	**TACROLIMUS**, tacrolimus 1 mg modified release capsule, 60 *(ADVAGRAF XL, Tacrolimus XR Sandoz)*	M	M,N

		From	To
10879N	**TACROLIMUS**, tacrolimus 2 mg capsule, 100 *(Tacrolimus Sandoz)*	M	M,N
11920J	**TACROLIMUS**, tacrolimus 3 mg modified release capsule, 50 *(ADVAGRAF XL, Tacrolimus XR Sandoz)*	M	M,N
6217F	**TACROLIMUS**, tacrolimus 5 mg capsule, 50 *(Pharmacor Tacrolimus 5, Prograf, Tacrograf, Tacrolimus Sandoz)*	M	M,N
9683P	**TACROLIMUS**, tacrolimus 5 mg modified release capsule, 30 *(ADVAGRAF XL, Tacrolimus XR Sandoz)*	M	M,N
9675F	**VALGANCICLOVIR**, valganciclovir 50 mg/mL powder for oral liquid, 100 mL *(Valcyte)*	M	M,N
6357N	**VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60 *(Valganciclovir Sandoz, Valganciclovir Viatris)*	M	M,N
13772W	**ZOLEDRONIC ACID**, zoledronic acid 4 mg/5 mL injection, 5 mL vial *(DEZTRON, Zoledronate-DRLA 4, Zoledronic Acid Accord)*	M	M,N

Alteration – Restriction

6232B	**CICLOSPORIN**, ciclosporin 10 mg capsule, 60 *(Neoral 10)*
6352H	**CICLOSPORIN**, ciclosporin 25 mg capsule, 30 *(APO-Ciclosporin, CICLOSPORIN-WGR, Neoral 25)*
6353J	**CICLOSPORIN**, ciclosporin 50 mg capsule, 30 *(APO-Ciclosporin, CICLOSPORIN-WGR, Neoral 50)*
6109M	**CICLOSPORIN**, ciclosporin 50 mg/mL injection, 10 x 1 mL ampoules *(Sandimmun)*
6354K	**CICLOSPORIN**, ciclosporin 100 mg capsule, 30 *(APO-Ciclosporin, CICLOSPORIN-WGR, Neoral 100)*
6125J	**CICLOSPORIN**, ciclosporin 100 mg/mL oral liquid, 50 mL *(Neoral)*
11545P	**DEFERASIROX**, deferasirox 90 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*
11548T	**DEFERASIROX**, deferasirox 90 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*
11558H	**DEFERASIROX**, deferasirox 90 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*
6499C	**DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Deferasirox Juno)*
11236J	**DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Deferasirox Juno)*
11241P	**DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Deferasirox Juno)*
11510T	**DEFERASIROX**, deferasirox 180 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*
11546Q	**DEFERASIROX**, deferasirox 180 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*
11557G	**DEFERASIROX**, deferasirox 180 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*
6500D	**DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Deferasirox Juno)*
11238L	**DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Deferasirox Juno)*
11244T	**DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Deferasirox Juno)*
11496C	**DEFERASIROX**, deferasirox 360 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox FCT MSN, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*
11511W	**DEFERASIROX**, deferasirox 360 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox FCT MSN, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*
11547R	**DEFERASIROX**, deferasirox 360 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox FCT MSN, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*
9600G	**DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Deferasirox Juno, Pharmacor Deferasirox)*
11232E	**DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Deferasirox Juno, Pharmacor Deferasirox)*
11243R	**DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Deferasirox Juno, Pharmacor Deferasirox)*
9638G	**DEFERIPRONE**, deferiprone 100 mg/mL oral liquid, 250 mL *(Ferriprox)*
6416Q	**DEFERIPRONE**, deferiprone 500 mg tablet, 100 *(Ferriprox)*

11724C **DEFERIPRONE**, deferiprone 1 g tablet, 50 *(Ferriprox)*

6113R **DESFERRIOXAMINE**, desferrioxamine mesilate 500 mg injection, 10 vials *(DBL Desferrioxamine Mesilate)*

6270B **DESFERRIOXAMINE**, desferrioxamine mesilate 2 g injection, 1 vial *(DBL Desferrioxamine Mesilate)*

6120D **DORNASE ALFA**, dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules *(Pulmozyme)*

14280N **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg granules [28] (&) ivacaftor 75 mg granules [28], 56 *(Trikafta)*

6459Y **EVEROLIMUS**, everolimus 250 microgram tablet, 60 *(Certican, Everocan)*

6460B **EVEROLIMUS**, everolimus 500 microgram tablet, 60 *(Certican, Everocan)*

6461C **EVEROLIMUS**, everolimus 750 microgram tablet, 60 *(Certican, Everocan)*

9582H **EVEROLIMUS**, everolimus 1 mg tablet, 60 *(Certican, Everocan)*

5830W **FILGRASTIM**, filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes *(Nivestim)*

2747N **FILGRASTIM**, filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes *(Zarzio)*

6291D **FILGRASTIM**, filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes *(Nivestim)*

2733W **FILGRASTIM**, filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes *(Zarzio)*

6292E **FILGRASTIM**, filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes *(Nivestim)*

11527Q **LANREOTIDE**, lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

2008Q **MANNITOL**, mannitol 40 mg powder for inhalation, 280 capsules *(Bronchitol)*

15508F **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

11518F **MIDOSTAURIN**, midostaurin 25 mg capsule, 112 *(Rydapt)*

6208R **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100 *(APO-Mycophenolate, Mycophenolate Sandoz, Pharmacor Mycophenolate 250)*

6209T **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50 *(ARX-MYCOPHENOLATE, Ceptolate, Mycophenolate GH, Mycophenolate Sandoz, Pharmacor Mycophenolate 500)*

6364Y **MYCOPHENOLATE**, mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL *(CellCept, Pharmacor Mycophenolate)*

11894B **OCTREOTIDE**, octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

6363X **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe *(Pelgraz, Ziextenzo)*

9748C **SIROLIMUS**, sirolimus 500 microgram tablet, 100 *(Rapamune)*

6436R **SIROLIMUS**, sirolimus 1 mg tablet, 100 *(Rapamune)*

6437T **SIROLIMUS**, sirolimus 1 mg/mL oral liquid, 60 mL *(Rapamune)*

6457W **SIROLIMUS**, sirolimus 2 mg tablet, 100 *(Rapamune)*

6328C **TACROLIMUS**, tacrolimus 500 microgram capsule, 100 *(Pacrolim, Pharmacor Tacrolimus 0.5, Prograf, Tacrograf, Tacrolimus Sandoz)*

9681M **TACROLIMUS**, tacrolimus 500 microgram modified release capsule, 30 *(ADVAGRAF XL, Tacrolimus XR Sandoz)*

10875J **TACROLIMUS**, tacrolimus 750 microgram capsule, 100 *(Tacrolimus Sandoz)*

6216E **TACROLIMUS**, tacrolimus 1 mg capsule, 100 *(Pacrolim, Pharmacor Tacrolimus 1, Prograf, Tacrograf, Tacrolimus Sandoz)*

9682N **TACROLIMUS**, tacrolimus 1 mg modified release capsule, 60 *(ADVAGRAF XL, Tacrolimus XR Sandoz)*

10879N **TACROLIMUS**, tacrolimus 2 mg capsule, 100 *(Tacrolimus Sandoz)*

11920J **TACROLIMUS**, tacrolimus 3 mg modified release capsule, 50 *(ADVAGRAF XL, Tacrolimus XR Sandoz)*

6217F **TACROLIMUS**, tacrolimus 5 mg capsule, 50 *(Pharmacor Tacrolimus 5, Prograf, Tacrograf, Tacrolimus Sandoz)*

9683P **TACROLIMUS**, tacrolimus 5 mg modified release capsule, 30 *(ADVAGRAF XL, Tacrolimus XR Sandoz)*

9675F **VALGANCICLOVIR**, valganciclovir 50 mg/mL powder for oral liquid, 100 mL *(Valcyte)*

6357N **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60 *(Valganciclovir Sandoz, Valganciclovir Viatris)*

13772W **ZOLEDRONIC ACID**, zoledronic acid 4 mg/5 mL injection, 5 mL vial *(DEZTRON, Zoledronate-DRLA 4, Zoledronic Acid Accord)*

Advance Notices

1 December 2026

Deletion – Item

6109M *Sandimmun, NV* – **CICLOSPORIN**, ciclosporin 50 mg/mL injection, 10 x 1 mL ampoules

6205N *Eprex 3000, JC* – **EPOETIN ALFA**, epoetin alfa 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

6206P *Eprex 4000, JC* – **EPOETIN ALFA**, epoetin alfa 4000 units/0.4 mL injection, 6 x 0.4 mL syringes

6204M *Eprex 2000, JC* – **EPOETIN ALFA**, epoetin alfa 2000 units/0.5 mL injection, 6 x 0.5 mL syringes

6251B *Eprex 1000, JC* – **EPOETIN ALFA**, epoetin alfa 1000 units/0.5 mL injection, 6 x 0.5 mL syringes

6302Q *Eprex 5000, JC* – **EPOETIN ALFA**, epoetin alfa 5000 units/0.5 mL injection, 6 x 0.5 mL syringes

6434P *Eprex 20,000, JC* – **EPOETIN ALFA**, epoetin alfa 20 000 units/0.5 mL injection, 6 x 0.5 mL syringes

6303R *Eprex 6000, JC* – **EPOETIN ALFA**, epoetin alfa 6000 units/0.6 mL injection, 6 x 0.6 mL syringes

6305W *Eprex 8000, JC* – **EPOETIN ALFA**, epoetin alfa 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

6339P *Eprex 40,000, JC* – **EPOETIN ALFA**, epoetin alfa 40 000 units/mL injection, 1 mL syringe

6207Q *Eprex 10000, JC* – **EPOETIN ALFA**, epoetin alfa 10 000 units/mL injection, 6 x 1 mL syringes

Deletion – Brand

11838C *Sevelamer Lupin, GQ* – **SEVELAMER**, sevelamer carbonate 800 mg tablet, 180

1 February 2027

Deletion – Brand

11510T *DEFERASIROX-TEVA, TB* – **DEFERASIROX**, deferasirox 180 mg tablet, 30

11546Q *DEFERASIROX-TEVA, TB* – **DEFERASIROX**, deferasirox 180 mg tablet, 30

11557G *DEFERASIROX-TEVA, TB* – **DEFERASIROX**, deferasirox 180 mg tablet, 30

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

15549J **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15555Q **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15571M **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15632R **CICLOSPORIN**, ciclosporin 10 mg capsule, 60 *(Neoral 10)*

15665L **CICLOSPORIN**, ciclosporin 25 mg capsule, 30 *(APO-Ciclosporin, CICLOSPORIN-WGR, Neoral 25)*

15642G **CICLOSPORIN**, ciclosporin 50 mg capsule, 30 *(APO-Ciclosporin, CICLOSPORIN-WGR, Neoral 50)*

15677D **CICLOSPORIN**, ciclosporin 100 mg capsule, 30 *(APO-Ciclosporin, CICLOSPORIN-WGR, Neoral 100)*

15654X **CICLOSPORIN**, ciclosporin 100 mg/mL oral liquid, 50 mL *(Neoral)*

15611P **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 50 mg + tezacaftor 25 mg + ivacaftor 37.5 mg tablet [56] (&) ivacaftor 75 mg tablet [28], 84 *(Trikafta)*

15626K **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 80 mg + tezacaftor 40 mg + ivacaftor 60 mg granules [28] (&) ivacaftor 59.5 mg granules [28], 56 *(Trikafta)*

15625J **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84 *(Trikafta)*

15657C **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg granules [28] (&) ivacaftor 75 mg granules [28], 56 *(Trikafta)*

15615W **IVACAFTOR**, ivacaftor 25 mg granules, 56 sachets *(Kalydeco)*

15616X **IVACAFTOR**, ivacaftor 25 mg granules, 56 sachets *(Kalydeco)*

15661G **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

15682J **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

15640E **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

15675B **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

15612Q **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

15630P **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

15645K **LANREOTIDE**, lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

15624H **LANREOTIDE**, lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

15607K **LANREOTIDE**, lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

15644J **LUMACAFTOR + IVACAFTOR**, lumacaftor 75 mg + ivacaftor 94 mg granules, 56 sachets *(Orkambi)*

15617Y **LUMACAFTOR + IVACAFTOR**, lumacaftor 100 mg + ivacaftor 125 mg tablet, 112 *(Orkambi)*

15641F **LUMACAFTOR + IVACAFTOR**, lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets *(Orkambi)*

15652T **LUMACAFTOR + IVACAFTOR**, lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets *(Orkambi)*

15618B **LUMACAFTOR + IVACAFTOR**, lumacaftor 200 mg + ivacaftor 125 mg tablet, 112 *(Orkambi)*

15681H **MYCOPHENOLATE**, mycophenolate 180 mg enteric tablet, 120 *(Mycophenolic Acid ARX, Myfortic)*

15651R **MYCOPHENOLATE**, mycophenolate 360 mg enteric tablet, 120 *(Mycophenolic Acid ARX, MYCOTEX, Myfortic)*

15670R **OCTREOTIDE**, octreotide 50 microgram/mL injection, 5 x 1 mL ampoules *(Octreotide (SUN), Octreotide GH, Sandostatin 0.05)*

15638C **OCTREOTIDE**, octreotide 100 microgram/mL injection, 5 x 1 mL ampoules *(Octreotide (SUN), Octreotide GH, Sandostatin 0.1)*

15672W **OCTREOTIDE**, octreotide 500 microgram/mL injection, 5 x 1 mL ampoules *(Octreotide (SUN), Octreotide GH, Sandostatin 0.5)*

15627L **OCTREOTIDE**, octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

15658D **OCTREOTIDE**, octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

15647M **OCTREOTIDE**, octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

15559X **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [9 x 8.3 mL vials], 1 pack *(Zolgensma)*

15594R **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [9 x 8.3 mL vials], 1 pack *(Zolgensma)*

15570L **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [10 x 8.3 mL vials], 1 pack *(Zolgensma)*

15600C **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [10 x 8.3 mL vials], 1 pack *(Zolgensma)*

15586H **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [11 x 8.3 mL vials], 1 pack *(Zolgensma)*

15595T **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [11 x 8.3 mL vials], 1 pack *(Zolgensma)*

15561B **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [12 x 8.3 mL vials], 1 pack *(Zolgensma)*

15596W **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [12 x 8.3 mL vials], 1 pack *(Zolgensma)*

15582D **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [13 x 8.3 mL vials], 1 pack *(Zolgensma)*

15589L **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [13 x 8.3 mL vials], 1 pack *(Zolgensma)*

15551L **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8 x 8.3 mL vials], 1 pack *(Zolgensma)*

15580B **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8 x 8.3 mL vials], 1 pack *(Zolgensma)*

15544D **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [9 x 8.3 mL vials], 1 pack *(Zolgensma)*

15547G **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [9 x 8.3 mL vials], 1 pack *(Zolgensma)*

15562C **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [10 x 8.3 mL vials], 1 pack *(Zolgensma)*

15598Y **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [10 x 8.3 mL vials], 1 pack *(Zolgensma)*

15546F **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [11 x 8.3 mL vials], 1 pack *(Zolgensma)*

15581C **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [11 x 8.3 mL vials], 1 pack *(Zolgensma)*

15579Y **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [12 x 8.3 mL vials], 1 pack *(Zolgensma)*

15587J **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [12 x 8.3 mL vials], 1 pack *(Zolgensma)*

15552M **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 10 x 8.3 mL vials *(Zolgensma)*

15554P **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 10 x 8.3 mL vials *(Zolgensma)*

15577W **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 11 x 8.3 mL vials *(Zolgensma)*

15588K **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 11 x 8.3 mL vials *(Zolgensma)*

15601D **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 12 x 8.3 mL vials *(Zolgensma)*

15602E **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 12 x 8.3 mL vials *(Zolgensma)*

15578X **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 13 x 8.3 mL vials *(Zolgensma)*

15604G **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 13 x 8.3 mL vials *(Zolgensma)*

15545E **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 14 x 8.3 mL vials *(Zolgensma)*

15553N **ONASEMNOGENE ABEPARVOVEC**, Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 14 x 8.3 mL vials *(Zolgensma)*

15569K **TEPROTUMUMAB**, Teprotumumab 500 mg injection, 1 vial *(Tepezza)*

15593Q **TEPROTUMUMAB**, Teprotumumab 500 mg injection, 1 vial *(Tepezza)*

15655Y **TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56 *(Symdeko)*

15667N **TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56 *(Symdeko)*

Addition – Brand

12444Y *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13212J *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

15138R *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

11533B *Deferasirox FCT MSN, VM* – **DEFERASIROX**, deferasirox 360 mg tablet, 30

11536E *Deferasirox FCT MSN, VM* – **DEFERASIROX**, deferasirox 360 mg tablet, 30

11555E *Deferasirox FCT MSN, VM* – **DEFERASIROX**, deferasirox 360 mg tablet, 30

9546K *Sevelamer Waymade, IX* – **SEVELAMER**, sevelamer hydrochloride 800 mg tablet, 180

Deletions

Deletion – Restriction

13276R **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 50 mg + tezacaftor 25 mg + ivacaftor 37.5 mg tablet [56] (&) ivacaftor 75 mg tablet [28], 84 *(Trikafta)*

14227T **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 80 mg + tezacaftor 40 mg + ivacaftor 60 mg granules [28] (&) ivacaftor 59.5 mg granules [28], 56 *(Trikafta)*

12936W **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84 *(Trikafta)*

14155B **IVACAFTOR**, ivacaftor 25 mg granules, 56 sachets *(Kalydeco)*

14156C **IVACAFTOR**, ivacaftor 25 mg granules, 56 sachets *(Kalydeco)*

11105L **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

14148P **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

11098D **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

14167P **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

10170G **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

14153X **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

5777C **LANREOTIDE**, lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

5778D **LANREOTIDE**, lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

5779E **LANREOTIDE**, lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

13798F **LUMACAFTOR + IVACAFTOR**, lumacaftor 75 mg + ivacaftor 94 mg granules, 56 sachets *(Orkambi)*

11465K **LUMACAFTOR + IVACAFTOR**, lumacaftor 100 mg + ivacaftor 125 mg tablet, 112 *(Orkambi)*

11866M **LUMACAFTOR + IVACAFTOR**, lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets *(Orkambi)*

11851R **LUMACAFTOR + IVACAFTOR**, lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets *(Orkambi)*

11466L **LUMACAFTOR + IVACAFTOR**, lumacaftor 200 mg + ivacaftor 125 mg tablet, 112 *(Orkambi)*

9503E **MYCOPHENOLATE**, mycophenolate 180 mg enteric tablet, 120 *(Mycophenolic Acid ARX, Myfortic)*

9504F **MYCOPHENOLATE**, mycophenolate 360 mg enteric tablet, 120 *(Mycophenolic Acid ARX, MYCOTEX, Myfortic)*

9508K **OCTREOTIDE**, octreotide 50 microgram/mL injection, 5 x 1 mL ampoules *(Octreotide (SUN), Octreotide GH, Sandostatin 0.05)*

9509L **OCTREOTIDE**, octreotide 100 microgram/mL injection, 5 x 1 mL ampoules *(Octreotide (SUN), Octreotide GH, Sandostatin 0.1)*

9510M **OCTREOTIDE**, octreotide 500 microgram/mL injection, 5 x 1 mL ampoules *(Octreotide (SUN), Octreotide GH, Sandostatin 0.5)*

10543X **OCTREOTIDE**, octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

10533J	**OCTREOTIDE**, octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*		
10550G	**OCTREOTIDE**, octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*		
11854X	**TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56 *(Symdeko)*		
11863J	**TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56 *(Symdeko)*		

Alterations

Alteration – Authorised Prescriber

		From	*To*
5631J	**CICLOSPORIN**, ciclosporin 50 mg/mL injection, 10 x 1 mL ampoules *(Sandimmun)*	M	M,N
11499F	**DEFERASIROX**, deferasirox 90 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
11519G	**DEFERASIROX**, deferasirox 90 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
11534C	**DEFERASIROX**, deferasirox 90 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
5654N	**DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Deferasirox Juno)*	M	M,N
11235H	**DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Deferasirox Juno)*	M	M,N
11247Y	**DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Deferasirox Juno)*	M	M,N
11500G	**DEFERASIROX**, deferasirox 180 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
11535D	**DEFERASIROX**, deferasirox 180 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
11556F	**DEFERASIROX**, deferasirox 180 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
5655P	**DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Deferasirox Juno)*	M	M,N
11239M	**DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Deferasirox Juno)*	M	M,N
11240N	**DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Deferasirox Juno)*	M	M,N
11533B	**DEFERASIROX**, deferasirox 360 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
11536E	**DEFERASIROX**, deferasirox 360 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
11555E	**DEFERASIROX**, deferasirox 360 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*	M	M,N
5656Q	**DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Deferasirox Juno, Pharmacor Deferasirox)*	M	M,N
11231D	**DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Deferasirox Juno, Pharmacor Deferasirox)*	M	M,N
11234G	**DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Deferasirox Juno, Pharmacor Deferasirox)*	M	M,N
5658T	**DEFERIPRONE**, deferiprone 100 mg/mL oral liquid, 250 mL *(Ferriprox)*	M	M,N
5657R	**DEFERIPRONE**, deferiprone 500 mg tablet, 100 *(Ferriprox)*	M	M,N
11747G	**DEFERIPRONE**, deferiprone 1 g tablet, 50 *(Ferriprox)*	M	M,N
5662B	**DESFERRIOXAMINE**, desferrioxamine mesilate 500 mg injection, 10 vials *(DBL Desferrioxamine Mesilate)*	M	M,N
5661Y	**DESFERRIOXAMINE**, desferrioxamine mesilate 2 g injection, 1 vial *(DBL Desferrioxamine Mesilate)*	M	M,N
5704F	**DORNASE ALFA**, dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules *(Pulmozyme)*	M	M,N

		From	*To*
5738B	**EVEROLIMUS**, everolimus 250 microgram tablet, 60 *(Certican, Everocan)*	M	M,N
5739C	**EVEROLIMUS**, everolimus 500 microgram tablet, 60 *(Certican, Everocan)*	M	M,N
5740D	**EVEROLIMUS**, everolimus 750 microgram tablet, 60 *(Certican, Everocan)*	M	M,N
5737Y	**EVEROLIMUS**, everolimus 1 mg tablet, 60 *(Certican, Everocan)*	M	M,N
5829T	**FILGRASTIM**, filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes *(Nivestim)*	M	M,N
2758E	**FILGRASTIM**, filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes *(Zarzio)*	M	M,N
5742F	**FILGRASTIM**, filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes *(Nivestim)*	M	M,N
2783L	**FILGRASTIM**, filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes *(Zarzio)*	M	M,N
5744H	**FILGRASTIM**, filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes *(Nivestim)*	M	M,N
11513Y	**LANREOTIDE**, lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*	M	M,N
2015C	**MANNITOL**, mannitol 40 mg powder for inhalation, 280 capsules *(Bronchitol)*	M	M,N
11505M	**MIDOSTAURIN**, midostaurin 25 mg capsule, 112 *(Rydapt)*	M	M,N
9501C	**MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100 *(APO-Mycophenolate, Mycophenolate Sandoz, Pharmacor Mycophenolate 250)*	M	M,N
9502D	**MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50 *(ARX-MYCOPHENOLATE, Ceptolate, Mycophenolate GH, Mycophenolate Sandoz, Pharmacor Mycophenolate 500)*	M	M,N
9500B	**MYCOPHENOLATE**, mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL *(CellCept, Pharmacor Mycophenolate)*	M	M,N
11893Y	**OCTREOTIDE**, octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*	M	M,N
9514R	**PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe *(Pelgraz, Ziextenzo)*	M	M,N
9747B	**SIROLIMUS**, sirolimus 500 microgram tablet, 100 *(Rapamune)*	M	M,N
9549N	**SIROLIMUS**, sirolimus 1 mg tablet, 100 *(Rapamune)*	M	M,N
9550P	**SIROLIMUS**, sirolimus 1 mg/mL oral liquid, 60 mL *(Rapamune)*	M	M,N
9548M	**SIROLIMUS**, sirolimus 2 mg tablet, 100 *(Rapamune)*	M	M,N
9558C	**TACROLIMUS**, tacrolimus 500 microgram capsule, 100 *(Pacrolim, Pharmacor Tacrolimus 0.5, Prograf, Tacrograf, Tacrolimus Sandoz)*	M	M,N
9664P	**TACROLIMUS**, tacrolimus 500 microgram modified release capsule, 30 *(ADVAGRAF XL, Tacrolimus XR Sandoz)*	M	M,N
10859M	**TACROLIMUS**, tacrolimus 750 microgram capsule, 100 *(Tacrolimus Sandoz)*	M	M,N
9560E	**TACROLIMUS**, tacrolimus 1 mg capsule, 100 *(Pacrolim, Pharmacor Tacrolimus 1, Prograf, Tacrograf, Tacrolimus Sandoz)*	M	M,N
9665Q	**TACROLIMUS**, tacrolimus 1 mg modified release capsule, 60 *(ADVAGRAF XL, Tacrolimus XR Sandoz)*	M	M,N
10860N	**TACROLIMUS**, tacrolimus 2 mg capsule, 100 *(Tacrolimus Sandoz)*	M	M,N
11907Q	**TACROLIMUS**, tacrolimus 3 mg modified release capsule, 50 *(ADVAGRAF XL, Tacrolimus XR Sandoz)*	M	M,N
9561F	**TACROLIMUS**, tacrolimus 5 mg capsule, 50 *(Pharmacor Tacrolimus 5, Prograf, Tacrograf, Tacrolimus Sandoz)*	M	M,N
9666R	**TACROLIMUS**, tacrolimus 5 mg modified release capsule, 30 *(ADVAGRAF XL, Tacrolimus XR Sandoz)*	M	M,N
9655E	**VALGANCICLOVIR**, valganciclovir 50 mg/mL powder for oral liquid, 100 mL *(Valcyte)*	M	M,N
9569P	**VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60 *(Valganciclovir Sandoz, Valganciclovir Viatris)*	M	M,N
13773X	**ZOLEDRONIC ACID**, zoledronic acid 4 mg/5 mL injection, 5 mL vial *(DEZTRON, Zoledronate-DRLA 4, Zoledronic Acid Accord)*	M	M,N

Alteration – Note

12951P **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack *(Zolgensma)*

13671M **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack *(Zolgensma)*

12977B **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack *(Zolgensma)*

13670L **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack *(Zolgensma)*

12942E **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack *(Zolgensma)*

13672N **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack *(Zolgensma)*

12976Y **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack *(Zolgensma)*

13680B **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack *(Zolgensma)*

12975X **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack *(Zolgensma)*

13677W **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack *(Zolgensma)*

12956X **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack *(Zolgensma)*

13662C **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack *(Zolgensma)*

12964H **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8 x 8.3 mL vials], 1 pack *(Zolgensma)*

13666G **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8 x 8.3 mL vials], 1 pack *(Zolgensma)*

12955W **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8.3 mL vial], 1 pack *(Zolgensma)*

13663D **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8.3 mL vial], 1 pack *(Zolgensma)*

12958B **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack *(Zolgensma)*

13669K **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack *(Zolgensma)*

12940C **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack *(Zolgensma)*

13682D **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack *(Zolgensma)*

12950N **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack *(Zolgensma)*

13683E **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack *(Zolgensma)*

12963G **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack *(Zolgensma)*

13681C **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack *(Zolgensma)*

12941D **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack *(Zolgensma)*

13679Y **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack *(Zolgensma)*

12952Q **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack *(Zolgensma)*

13668J **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack *(Zolgensma)*

12957Y **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 2 x 8.3 mL vials *(Zolgensma)*

13674Q **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 2 x 8.3 mL vials *(Zolgensma)*

12961E **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 3 x 8.3 mL vials *(Zolgensma)*

13678X **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 3 x 8.3 mL vials *(Zolgensma)*

12971Q **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 4 x 8.3 mL vials *(Zolgensma)*

13665F **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 4 x 8.3 mL vials *(Zolgensma)*

12962F **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 5 x 8.3 mL vials *(Zolgensma)*

13667H **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 5 x 8.3 mL vials *(Zolgensma)*

12973T **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 6 x 8.3 mL vials *(Zolgensma)*

13664E **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 6 x 8.3 mL vials *(Zolgensma)*

12954T **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 7 x 8.3 mL vials *(Zolgensma)*

13675R **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 7 x 8.3 mL vials *(Zolgensma)*

12974W **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 8 x 8.3 mL vials *(Zolgensma)*

13673P **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 8 x 8.3 mL vials *(Zolgensma)*

12949M **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 9 x 8.3 mL vials *(Zolgensma)*

13676T **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 9 x 8.3 mL vials *(Zolgensma)*

Alteration – Restriction

5632K **CICLOSPORIN**, ciclosporin 10 mg capsule, 60 *(Neoral 10)*

5634M **CICLOSPORIN**, ciclosporin 25 mg capsule, 30 *(APO-Ciclosporin, CICLOSPORIN-WGR, Neoral 25)*

5635N **CICLOSPORIN**, ciclosporin 50 mg capsule, 30 *(APO-Ciclosporin, CICLOSPORIN-WGR, Neoral 50)*

5631J **CICLOSPORIN**, ciclosporin 50 mg/mL injection, 10 x 1 mL ampoules *(Sandimmun)*

5636P **CICLOSPORIN**, ciclosporin 100 mg capsule, 30 *(APO-Ciclosporin, CICLOSPORIN-WGR, Neoral 100)*

5633L **CICLOSPORIN**, ciclosporin 100 mg/mL oral liquid, 50 mL *(Neoral)*

11499F **DEFERASIROX**, deferasirox 90 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*

11519G **DEFERASIROX**, deferasirox 90 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*

11534C **DEFERASIROX**, deferasirox 90 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*

5654N **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Deferasirox Juno)*

11235H **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Deferasirox Juno)*

11247Y **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28 *(Deferasirox Juno)*

11500G **DEFERASIROX**, deferasirox 180 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*

11535D **DEFERASIROX**, deferasirox 180 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*

11556F **DEFERASIROX**, deferasirox 180 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*

5655P **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Deferasirox Juno)*

11239M **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Deferasirox Juno)*

11240N **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28 *(Deferasirox Juno)*

11533B **DEFERASIROX**, deferasirox 360 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox FCT MSN, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*

11536E **DEFERASIROX**, deferasirox 360 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox FCT MSN, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*

11555E **DEFERASIROX**, deferasirox 360 mg tablet, 30 *(DEFERAMED, Deferasirox ARX, Deferasirox FCT MSN, Deferasirox Sandoz, DEFERASIROX-TEVA, Eferas, Jadenu, Pharmacor Deferasirox FC)*

5656Q **DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Deferasirox Juno, Pharmacor Deferasirox)*

11231D **DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Deferasirox Juno, Pharmacor Deferasirox)*

11234G **DEFERASIROX**, deferasirox 500 mg dispersible tablet, 28 *(Deferasirox Juno, Pharmacor Deferasirox)*

5658T **DEFERIPRONE**, deferiprone 100 mg/mL oral liquid, 250 mL *(Ferriprox)*

5657R **DEFERIPRONE**, deferiprone 500 mg tablet, 100 *(Ferriprox)*

11747G **DEFERIPRONE**, deferiprone 1 g tablet, 50 *(Ferriprox)*

5662B **DESFERRIOXAMINE**, desferrioxamine mesilate 500 mg injection, 10 vials *(DBL Desferrioxamine Mesilate)*

5661Y **DESFERRIOXAMINE**, desferrioxamine mesilate 2 g injection, 1 vial *(DBL Desferrioxamine Mesilate)*

5704F **DORNASE ALFA**, dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules *(Pulmozyme)*

14228W **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**, elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg granules [28] (&) ivacaftor 75 mg granules [28], 56 *(Trikafta)*

5738B **EVEROLIMUS**, everolimus 250 microgram tablet, 60 *(Certican, Everocan)*

5739C **EVEROLIMUS**, everolimus 500 microgram tablet, 60 *(Certican, Everocan)*

5740D **EVEROLIMUS**, everolimus 750 microgram tablet, 60 *(Certican, Everocan)*

5737Y **EVEROLIMUS**, everolimus 1 mg tablet, 60 *(Certican, Everocan)*

5829T **FILGRASTIM**, filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes *(Nivestim)*

2758E **FILGRASTIM**, filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes *(Zarzio)*

5742F **FILGRASTIM**, filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes *(Nivestim)*

2783L **FILGRASTIM**, filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes *(Zarzio)*

5744H **FILGRASTIM**, filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes *(Nivestim)*

11513Y **LANREOTIDE**, lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

2015C **MANNITOL**, mannitol 40 mg powder for inhalation, 280 capsules *(Bronchitol)*

15511J **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

11505M **MIDOSTAURIN**, midostaurin 25 mg capsule, 112 *(Rydapt)*

9501C **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100 *(APO-Mycophenolate, Mycophenolate Sandoz, Pharmacor Mycophenolate 250)*

9502D **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50 *(ARX-MYCOPHENOLATE, Ceptolate, Mycophenolate GH, Mycophenolate Sandoz, Pharmacor Mycophenolate 500)*

9500B **MYCOPHENOLATE**, mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL *(CellCept, Pharmacor Mycophenolate)*

11893Y **OCTREOTIDE**, octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

12951P **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack *(Zolgensma)*

13671M **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack *(Zolgensma)*

12977B **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack *(Zolgensma)*

13670L **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack *(Zolgensma)*

12942E **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack *(Zolgensma)*

13672N **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack *(Zolgensma)*

12976Y **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack *(Zolgensma)*

13680B **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack *(Zolgensma)*

12975X **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack *(Zolgensma)*

13677W **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack *(Zolgensma)*

12956X **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack *(Zolgensma)*

13662C **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack *(Zolgensma)*

12964H **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8 x 8.3 mL vials], 1 pack *(Zolgensma)*

13666G **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8 x 8.3 mL vials], 1 pack *(Zolgensma)*

12955W **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8.3 mL vial], 1 pack *(Zolgensma)*

13663D **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8.3 mL vial], 1 pack *(Zolgensma)*

12958B **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack *(Zolgensma)*

13669K **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack *(Zolgensma)*

12940C **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack *(Zolgensma)*

13682D **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack *(Zolgensma)*

12950N **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack *(Zolgensma)*

13683E **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack *(Zolgensma)*

12963G **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack *(Zolgensma)*

13681C **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack *(Zolgensma)*

12941D **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack *(Zolgensma)*

13679Y **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack *(Zolgensma)*

12952Q **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack *(Zolgensma)*

13668J **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack *(Zolgensma)*

12957Y **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 2 x 8.3 mL vials *(Zolgensma)*

13674Q **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 2 x 8.3 mL vials *(Zolgensma)*

12961E **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 3 x 8.3 mL vials *(Zolgensma)*

13678X **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 3 x 8.3 mL vials *(Zolgensma)*

12971Q **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 4 x 8.3 mL vials *(Zolgensma)*

13665F **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 4 x 8.3 mL vials *(Zolgensma)*

12962F **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 5 x 8.3 mL vials *(Zolgensma)*

13667H **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 5 x 8.3 mL vials *(Zolgensma)*

12973T **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 6 x 8.3 mL vials *(Zolgensma)*

13664E **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 6 x 8.3 mL vials *(Zolgensma)*

12954T **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 7 x 8.3 mL vials *(Zolgensma)*

13675R **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 7 x 8.3 mL vials *(Zolgensma)*

12974W **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 8 x 8.3 mL vials *(Zolgensma)*

13673P **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 8 x 8.3 mL vials *(Zolgensma)*

12949M **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 9 x 8.3 mL vials *(Zolgensma)*

13676T **ONASEMNOGENE ABEPARVOVEC**, onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 9 x 8.3 mL vials *(Zolgensma)*

9514R **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe *(Pelgraz, Ziextenzo)*

9747B **SIROLIMUS**, sirolimus 500 microgram tablet, 100 *(Rapamune)*

9549N **SIROLIMUS**, sirolimus 1 mg tablet, 100 *(Rapamune)*

9550P **SIROLIMUS**, sirolimus 1 mg/mL oral liquid, 60 mL *(Rapamune)*

9548M **SIROLIMUS**, sirolimus 2 mg tablet, 100 *(Rapamune)*

9558C **TACROLIMUS**, tacrolimus 500 microgram capsule, 100 *(Pacrolim, Pharmacor Tacrolimus 0.5, Prograf, Tacrograf, Tacrolimus Sandoz)*

9664P **TACROLIMUS**, tacrolimus 500 microgram modified release capsule, 30 *(ADVAGRAF XL, Tacrolimus XR Sandoz)*

10859M **TACROLIMUS**, tacrolimus 750 microgram capsule, 100 *(Tacrolimus Sandoz)*

9560E **TACROLIMUS**, tacrolimus 1 mg capsule, 100 *(Pacrolim, Pharmacor Tacrolimus 1, Prograf, Tacrograf, Tacrolimus Sandoz)*

9665Q **TACROLIMUS**, tacrolimus 1 mg modified release capsule, 60 *(ADVAGRAF XL, Tacrolimus XR Sandoz)*

10860N **TACROLIMUS**, tacrolimus 2 mg capsule, 100 *(Tacrolimus Sandoz)*

11907Q **TACROLIMUS**, tacrolimus 3 mg modified release capsule, 50 *(ADVAGRAF XL, Tacrolimus XR Sandoz)*

9561F **TACROLIMUS**, tacrolimus 5 mg capsule, 50 *(Pharmacor Tacrolimus 5, Prograf, Tacrograf, Tacrolimus Sandoz)*

9666R **TACROLIMUS**, tacrolimus 5 mg modified release capsule, 30 *(ADVAGRAF XL, Tacrolimus XR Sandoz)*

9655E **VALGANCICLOVIR**, valganciclovir 50 mg/mL powder for oral liquid, 100 mL *(Valcyte)*

9569P **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60 *(Valganciclovir Sandoz, Valganciclovir Viatris)*

13773X **ZOLEDRONIC ACID**, zoledronic acid 4 mg/5 mL injection, 5 mL vial *(DEZTRON, Zoledronate-DRLA 4, Zoledronic Acid Accord)*

Advance Notices

1 December 2026

Deletion – Item

5631J *Sandimmun, NV* – **CICLOSPORIN**, ciclosporin 50 mg/mL injection, 10 x 1 mL ampoules

5720C *Eprex 3000, JC* – **EPOETIN ALFA**, epoetin alfa 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

5721D *Eprex 4000, JC* – **EPOETIN ALFA**, epoetin alfa 4000 units/0.4 mL injection, 6 x 0.4 mL syringes

5713Q *Eprex 20,000, JC* – **EPOETIN ALFA**, epoetin alfa 20 000 units/0.5 mL injection, 6 x 0.5 mL syringes

5714R *Eprex 1000, JC* – **EPOETIN ALFA**, epoetin alfa 1000 units/0.5 mL injection, 6 x 0.5 mL syringes

5715T *Eprex 5000, JC* – **EPOETIN ALFA**, epoetin alfa 5000 units/0.5 mL injection, 6 x 0.5 mL syringes

5719B *Eprex 2000, JC* – **EPOETIN ALFA**, epoetin alfa 2000 units/0.5 mL injection, 6 x 0.5 mL syringes

5716W *Eprex 6000, JC* – **EPOETIN ALFA**, epoetin alfa 6000 units/0.6 mL injection, 6 x 0.6 mL syringes

5717X *Eprex 8000, JC* – **EPOETIN ALFA**, epoetin alfa 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

5718Y *Eprex 40,000, JC* – **EPOETIN ALFA**, epoetin alfa 40 000 units/mL injection, 1 mL syringe

5722E *Eprex 10000, JC* – **EPOETIN ALFA**, epoetin alfa 10 000 units/mL injection, 6 x 1 mL syringes

Deletion – Brand

11855Y *Sevelamer Lupin, GQ* – **SEVELAMER**, sevelamer carbonate 800 mg tablet, 180

1 February 2027

Deletion – Brand

11500G *DEFERASIROX-TEVA, TB* – **DEFERASIROX**, deferasirox 180 mg tablet, 30

11535D *DEFERASIROX-TEVA, TB* – **DEFERASIROX**, deferasirox 180 mg tablet, 30

11556F *DEFERASIROX-TEVA, TB* – **DEFERASIROX**, deferasirox 180 mg tablet, 30

Highly Specialised Drugs Program (Community Access)

Additions

Addition – Item

15668P **LANREOTIDE**, lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

15636Y **LANREOTIDE**, lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

15619C **LANREOTIDE**, lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

15679F **LANREOTIDE**, lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

15609M **OCTREOTIDE**, octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

15659E **OCTREOTIDE**, octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

15669Q **OCTREOTIDE**, octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

Deletions

Deletion – Restriction

11315M **LANREOTIDE**, lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

11316N **LANREOTIDE**, lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

11289E **LANREOTIDE**, lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

11736Q **LANREOTIDE**, lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe *(Mytolac, Somatuline Autogel)*

11501H **OCTREOTIDE**, octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

11537F **OCTREOTIDE**, octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

11512X **OCTREOTIDE**, octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

Alterations

Alteration – Authorised Prescriber

		From	*To*
10289M	**CLOZAPINE**, clozapine 25 mg tablet, 100 *(Clopine 25, Clozaril 25, Clozitor)*	M	M,N
10302F	**CLOZAPINE**, clozapine 50 mg tablet, 100 *(Clopine 50, Clozitor)*	M	M,N
10341G	**CLOZAPINE**, clozapine 50 mg/mL oral liquid, 100 mL *(Clopine Suspension)*	M	M,N
11422E	**CLOZAPINE**, clozapine 50 mg/mL oral liquid, 100 mL *(Versacloz)*	M	M,N
10358E	**CLOZAPINE**, clozapine 100 mg tablet, 100 *(Clopine 100, Clozaril 100, Clozitor)*	M	M,N
10288L	**CLOZAPINE**, clozapine 200 mg tablet, 100 *(Clopine 200, Clozitor)*	M	M,N
11896D	**OCTREOTIDE**, octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*	M	M,N

Alteration – Restriction

10289M **CLOZAPINE**, clozapine 25 mg tablet, 100 *(Clopine 25, Clozaril 25, Clozitor)*

10302F **CLOZAPINE**, clozapine 50 mg tablet, 100 *(Clopine 50, Clozitor)*

10341G **CLOZAPINE**, clozapine 50 mg/mL oral liquid, 100 mL *(Clopine Suspension)*

11422E **CLOZAPINE**, clozapine 50 mg/mL oral liquid, 100 mL *(Versacloz)*

10358E **CLOZAPINE**, clozapine 100 mg tablet, 100 *(Clopine 100, Clozaril 100, Clozitor)*

10288L **CLOZAPINE**, clozapine 200 mg tablet, 100 *(Clopine 200, Clozitor)*

11896D **OCTREOTIDE**, octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

Advance Notices

1 January 2027

Deletion – Item

13320C *Sublocade, IR* – **BUPRENORPHINE**, buprenorphine 100 mg/0.5 mL modified release injection, 0.5 mL syringe

13327K *Sublocade, IR* – **BUPRENORPHINE**, buprenorphine 300 mg/1.5 mL modified release injection, 1.5 mL syringe

1 February 2027

Deletion – Item

10319D *Viramune, BY* – **NEVIRAPINE**, nevirapine 10 mg/mL oral liquid, 240 mL

Botulinum Toxin Program

Additions

Addition – Item

15574Q **INCOBOTULINUMTOXINA**, incobotulinumtoxinA 100 units injection, 1 vial *(Xeomin)*

Repatriation Pharmaceutical Benefits

Advance Notices

1 December 2026

Deletion – Item

4434J *Aci-Jel, CU* – **ACETIC ACID + OXYQUINOLINE + RICINOLEIC ACID**, acetic acid 0.94% + oxyquinoline sulfate 0.025% + ricinoleic acid 0.75% vaginal gel, 100 g

10017F *Allevyn Life 66801067, SN* – **DRESSING FOAM WITH SILICONE**, dressing foam with silicone 10.3 cm x 10.3 cm dressing, 10

10029W *Allevyn Life 66801068, SN* – **DRESSING FOAM WITH SILICONE**, dressing foam with silicone 12.9 cm x 12.9 cm dressing, 10

10023M *Allevyn Life 66801069, SN* – **DRESSING FOAM WITH SILICONE**, dressing foam with silicone 15.4 cm x 15.4 cm dressing, 10

10021K *Allevyn Life 66801070, SN* – **DRESSING FOAM WITH SILICONE**, dressing foam with silicone 21 cm x 21 cm dressing, 10

10586E *Petrus Pharmaceuticals Pty Ltd, PP* – **GLYCEROL**, glycerol 700 mg suppository, 12

10596Q *Petrus Pharmaceuticals Pty Ltd, PP* – **GLYCEROL**, glycerol 1.4 g suppository, 12

4246L *Petrus Pharmaceuticals Pty Ltd, PP* – **GLYCEROL**, glycerol 2.8 g suppository, 12

4306P *Lubri-Gel, PP* – **LUBRICATING AGENT**, lubricating agent gel, 100 g

Prescriber Bag

SALBUTAMOL

salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

13828T	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	‡1.00	59.53	PMS-SALBUTAMOL (Canada) [RQ]

General Pharmaceutical Benefits

ACARBOSE

Note Pharmaceutical benefits that have the form acarbose 100 mg tablet can be substituted for Acarbose 100 mg tablets (Morningside Healthcare, UK) in the case of a shortage.

acarbose 100 mg tablet, 90

8189B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	0.00	34.27	25.00	[a] Acarbose Viatris [AL]	[a] GLYBOSAY [RW]

acarbose 100 mg tablet, 90

14722W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	0.00	117.24	25.00	[a] Acarbose 100 mg tablets (Morningside Healthcare, UK) [LM]

ACARBOSE

Note Pharmaceutical benefits that have the form acarbose 50 mg tablet can be substituted for Acarbose 50 mg tablets (Morningside Healthcare, UK) in the case of a shortage.

acarbose 50 mg tablet, 90

14735M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	0.00	95.92	25.00	[a] Acarbose 50 mg tablets (Morningside Healthcare, UK) [LM]

ACARBOSE

Note Pharmaceutical benefits that have the form acarbose 100 mg tablet can be substituted for Acarbose 100 mg tablets (Morningside Healthcare, UK) in the case of a shortage.

Restricted benefit

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

acarbose 100 mg tablet, 90

13869Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*54.18	25.00	[a] Acarbose Viatris [AL]	[a] GLYBOSAY [RW]

acarbose 100 mg tablet, 90

14734L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	0.00	*225.12	25.00	[a] Acarbose 100 mg tablets (Morningside Healthcare, UK) [LM]

ACARBOSE

Note Pharmaceutical benefits that have the form acarbose 50 mg tablet can be substituted for Acarbose 50 mg tablets (Morningside Healthcare, UK) in the case of a shortage.

Restricted benefit

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

acarbose 50 mg tablet, 90

13955L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*42.48	25.00	[a] Acarbose Viatris [AL]	[a] GLYBOSAY [RW]

acarbose 50 mg tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14726C NP	2	5	0.00	*180.64	25.00	[a] Acarbose 50 mg tablets (Morningside Healthcare, UK) [LM]

ADALIMUMAB

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

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

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

Authority Required (STREAMLINED)

15445

Vision threatening non-infectious uveitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 weeks under this restriction per authority application.

Treatment criteria:

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
15557T	2	5	0.00	*606.96	25.00	[a] Amgevita [AN]

ADALIMUMAB

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

Authority Required

Vision threatening non-infectious uveitis

Treatment Phase: Balance of Supply

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition to complete one of the following: (i) 25 weeks for initial treatment; (ii) 25 weeks for recommencement treatment; (iii) 24 weeks for continuing treatment; (iv) 24 weeks for transitioning from non-PBS to PBS-subsidised treatment.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
15563D	2	0	0.00	*606.96	25.00	[a] Amgevita [AN]

ADALIMUMAB

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

Authority Required (STREAMLINED)

17736

Enthesitis/spondylitis related juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response is defined as an improvement from baseline in the Juvenile Spondyloarthritis Disease Activity Index score by at least 30% or an improvement in the persistent symptoms of axial spondylitis or sacroiliitis.

If a patient fails to demonstrate a response to treatment with this drug, they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition until 2 years have elapsed. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 2 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed, and the date of the first application submitted for approval.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15566G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	0.00	*606.96	25.00	[a] Amgevita [AN]

ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to

prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017:

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

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

Authority Required (STREAMLINED)

16991

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; **OR**
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be 6 years of age or older.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15575R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	0.00	*606.96	25.00	[a] Amgevita [AN]

ADALIMUMAB

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

Authority Required

Vision threatening non-infectious uveitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrated or sustained an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 weeks under this restriction per authority application.

Treatment criteria:

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15583E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	0.00	*606.96	25.00	[a] Amgevita [AN]

ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial restriction (Initial 1, 2 or 3), **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15590M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	0	0.00	*606.96	25.00	[a] Amgevita [AN]

ADALIMUMAB

Note The assessment for Juvenile Spondyloarthritis Disease Activity Index score is available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4245319/table/T2/.

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

Authority Required

Enthesitis/spondylitis related juvenile idiopathic arthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2026, **AND**
- Patient must have, prior to initiating treatment with this drug for this condition, a diagnosis of enthesitis/spondylitis related juvenile idiopathic arthritis defined by at least one of the following: (i) peripheral arthritis and enthesitis, (ii) inflammatory sacroiliitis on Magnetic Resonance Imaging (MRI) plus at least 3 months of inflammatory back pain, (iii) arthritis or enthesitis plus at least 2 of: (a) sacroiliac joint tenderness, (b) inflammatory back pain, (c) presence of HLA-B27 antigen, (d) acute (symptomatic) anterior uveitis, (e) history of spondyloarthritis in a first-degree relative, **AND**

- Patient must have, prior to initiating treatment with this drug for this condition, failed to achieve an adequate response for axial disease (sacroiliitis and/or spondylitis), following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs) whilst completing an appropriate exercise program, for a total period of 3 months; **OR**
- Patient must have, prior to initiating treatment with this drug for this condition, failed to achieve an adequate response for peripheral disease (arthritis and/or enthesitis) following treatment with at least 2 NSAIDs, and either: (i) methotrexate at a dose of 15 mg per square metre (maximum 20 mg) weekly, (ii) sulfasalazine at a dose of 20 mg/kg (maximum 1 g) twice daily, whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age, prior to commencement of this drug for this condition.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If treatment with methotrexate, sulfasalazine or NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to methotrexate, sulfasalazine or NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Juvenile Spondyloarthritis Disease Activity Index score greater than 2; or

(b) persistent symptoms of axial spondylitis or sacroiliitis with prior confirmatory Magnetic Resonance Imaging (MRI) assessed by a clinician experienced with juvenile spondyloarthropathy.

The following must be provided at the time of application and documented in the patient's medical records:

(1) details of prior treatment including dose and duration of treatment; and

(i) if applicable, a baseline Juvenile Spondyloarthritis Disease Activity Index score; or

(ii) if applicable, the current Juvenile Spondyloarthritis Disease Activity Index score; or

(iii) if applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) of the MRI demonstrating inflammatory spondylitis or sacroiliitis; or

(iv) if applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) demonstrating the presence of HLA-B27.

The Juvenile Spondyloarthritis Disease Activity Index score must be assessed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

An adequate response is defined as an improvement from baseline in the Juvenile Spondyloarthritis Disease Activity Index score by at least 30% or an improvement in the persistent symptoms of axial spondylitis or sacroiliitis.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug, they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition until 2 years have elapsed. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15548H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	0.00	*606.96	25.00	[a] Amgevita [AN]

ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response,

the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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

Authority Required (STREAMLINED)

18991

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have both: (i) a total PCDAI score of 40 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; **OR**
- Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition under this treatment phase. Patients may re-trial treatment with this drug under the 'Initial 2' treatment phase if eligible. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15567H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	0.00	*606.96	25.00	[a] Amgevita [AN]

ADALIMUMAB

Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

Assessment of response to initial treatment:

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

Continuing treatment:

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

Re-treatment (etanercept only):

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Authority Required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Population criteria:

- Patient must have been under 18 years of age at the time of initial treatment with this drug.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Authority Required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Population criteria:

- Patient must have been under 18 years of age at the time of initial treatment with this drug.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15550K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	0.00	*606.96	25.00	[a] Amgevita [AN]

ADALIMUMAB

Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

Assessment of response to initial treatment:

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

Continuing treatment:

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an

initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

Re-treatment (etanercept only):

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

Authority Required (STREAMLINED)

17065

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Population criteria:

- Patient must have been under 18 years of age at the time of initial treatment with this drug.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Authority Required (STREAMLINED)

16999

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Population criteria:

- Patient must have been under 18 years of age at the time of initial treatment with this drug.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15558W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	0.00	*606.96	25.00	[a] Amgevita [AN]

ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017:

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

Authority Required

Moderate to severe ulcerative colitis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; **OR**
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction for patients who:

(i) received fewer than 5 repeats at the time of application; and/or

(ii) required changes to their dosing regimen during this treatment phase.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority Required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15564E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	0.00	*606.96	25.00	[a] Amgevita [AN]

ADALIMUMAB

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

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

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

Authority Required

Vision threatening non-infectious uveitis

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have non-infectious uveitis that is vision threatening with the diagnosis confirmed by an ophthalmologist, rheumatologist, or immunologist, **AND**
- Patient must have failed to achieve an adequate response to corticosteroid therapy in combination with at least 1 immunosuppressive agent; **OR**
- Patient must have flared when corticosteroid therapy was tapered to a dose of less than or equal to 7.5 mg per day of prednisone or equivalent while on immunomodulatory therapy; **OR**
- Patient must have failed to achieve an adequate response to at least one immunosuppressive agent in patients for whom corticosteroids are not clinically appropriate; **OR**
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to corticosteroid and immunomodulatory therapy, **AND**
- The treatment must not exceed 25 weeks under this restriction.

Treatment criteria:

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Vision threatening disease is defined as at least 1 of the following:

(a) A decrease in visual acuity of at least 10 letters using an ETDRS chart or equivalent;

(b) A 2-step increase in anterior chamber cells or vitreous haze;

(c) New retinal vasculitis;

(d) New retinal or choroidal lesions;

(e) Other signs of disease progression including visual field changes or electroretinogram changes

A failure to achieve an adequate response is defined as failure to meet one or more of the below criteria:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

Details of prior immunomodulatory agent and corticosteroid treatment, or details of contraindications or developed intolerances necessitating treatment withdrawal, must be documented in the patient's medical record.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include details of vision threatening disease.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

Vision threatening non-infectious uveitis

Treatment Phase: Recommencement of treatment

Clinical criteria:

- Patient must have a documented history of non-infectious uveitis that is vision threatening, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment prior to having a break in therapy with this drug for this condition, **AND**

- The treatment must not exceed 25 weeks under this restriction.

Treatment criteria:

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15565F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	6	0.00	*606.96	25.00	[a] Amgevita [AN]

ADALIMUMAB

Note The assessment for Juvenile Spondyloarthritis Disease Activity Index score is available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4245319/table/T2/.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

Authority Required

Enthesitis/spondylitis related juvenile idiopathic arthritis

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a diagnosis of enthesitis/spondylitis related juvenile idiopathic arthritis defined by at least one of the following: (i) peripheral arthritis and enthesitis, (ii) inflammatory sacroiliitis on Magnetic Resonance Imaging (MRI) plus at least 3 months of inflammatory back pain, (iii) arthritis or enthesitis plus at least 2 of: (a) sacroiliac joint tenderness, (b) inflammatory back pain, (c) presence of HLA-B27 antigen, (d) acute (symptomatic) anterior uveitis, (e) history of spondyloarthritis in a first-degree relative, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have had a break in treatment of at least 2 years from the most recently prescribed PBS-subsidised biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response for axial disease (sacroiliitis and/or spondylitis), following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs) whilst completing an appropriate exercise program, for a total period of 3 months; **OR**
- Patient must have failed to achieve an adequate response for peripheral disease (arthritis and/or enthesitis) following treatment with at least 2 NSAIDs, and either: (i) methotrexate at a dose of 15 mg per square metre (maximum 20 mg) weekly, (ii) sulfasalazine at a dose of 20 mg/kg (maximum 1 g) twice daily, whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If treatment with methotrexate, sulfasalazine or NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to methotrexate, sulfasalazine or NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Juvenile Spondyloarthritis Disease Activity Index score greater than 2; or

(b) persistent symptoms of axial spondylitis or sacroiliitis with prior confirmatory Magnetic Resonance Imaging (MRI) assessed by a clinician experienced with juvenile spondyloarthropathy.

The following must be provided at the time of application and documented in the patient's medical records:

(1) details of prior treatment including dose and duration of treatment; and

(i) if applicable, the baseline Juvenile Spondyloarthritis Disease Activity Index score; or

(ii) if applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) of the MRI demonstrating inflammatory spondylitis or sacroiliitis; or

(iii) if applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) demonstrating the presence of HLA-B27.

The Juvenile Spondyloarthritis Disease Activity Index score must be assessed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug, they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition until 2 years have elapsed. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

Enthesitis/spondylitis related juvenile idiopathic arthritis

Treatment Phase: Initial treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15572N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	0.00	*606.96	25.00	[a] Amgevita [AN]

ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.

An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must not have achieved an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy with a thiopurine at a clinically optimised dose, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; **OR**
- Patient must have a documented contraindication to each of prednisolone (or equivalent), a thiopurine, and methotrexate; **OR**
- Patient must have features of high-risk or complicated Crohn disease defined as those with any of the following: (i) perianal disease, (ii) stricturing or penetrating behaviour, (iii) severe delayed growth (growth velocity at least 2 standard deviations below the mean for age and sex, or a drop of at least 1 major centile band), **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40; **OR**
- Patient must have extensive intestinal inflammation of the small intestine as evidenced by radiological imaging, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) current PCDAI score and the date of assessment; or

(c) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must not have previously received this drug for this condition in this treatment cycle; **OR**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response; **OR**
- Patient must have: (i) received this drug in this treatment cycle, (ii) not demonstrated/maintained an adequate response to this drug once in this treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the PCDAI score and the date of assessment; or

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' clinical and treatment criteria when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15591N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	0.00	*606.96	25.00	[a] Amgevita [AN]

ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017:

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.

An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.

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

Authority Required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); **OR**
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:
(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; **OR**
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; **OR**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of

biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); **OR**
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15584F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	0.00	*606.96	25.00	[a] Amgevita [AN]

ADALIMUMAB

Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

Assessment of response to initial treatment:

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

Continuing treatment:

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be

deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

Re-treatment (etanercept only):

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

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

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

Authority Required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naive patient

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Population criteria:

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.

A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) the PASI score that followed each prior therapy trialled;

(iv) the date the PASI scores were determined.

Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years

Clinical criteria:

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Population criteria:

- Patient must be under 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.

Response to preceding supply:

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Change in therapy:

If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above

Recommencing therapy:

If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:

(i) an absence of an adequate response; or

(ii) an intolerance to that treatment; or

(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; **OR**
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**
- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; **OR**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Population criteria:

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority Required

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2 or 3 treatment (Whole body, or, face/hand/foot)

Clinical criteria:

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of 17 weeks of treatment available under any of the initial treatment phases.

Treatment criteria:

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 3 doses available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

Clinical criteria:

- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Population criteria:

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;

(iv) the dates that response assessments were determined.

Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);

(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years

Clinical criteria:

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Population criteria:

- Patient must be under 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.

Response to preceding supply:

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Change in therapy:

If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above

Recommencing therapy:

If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:

(i) an absence of an adequate response; or

(ii) an intolerance to that treatment; or

(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
15573P	2	4	0.00	*606.96	25.00	[a] Amgevita [AN]

ALBENDAZOLE

Note Pharmaceutical benefits that have the brand Albendazole (Micro Labs, Germany) may be substituted for pharmaceutical benefits that have the brand Eskazole in the case of a shortage.

Authority Required (STREAMLINED)

5607

Hydatid disease

Clinical criteria:

- The treatment must be in conjunction with surgery; **OR**
- The treatment must be used when a surgical cure cannot be achieved; **OR**
- The treatment must be used when surgery cannot be used.

albendazole 400 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8459F	1	2	0.00	114.00	25.00	[a] Eskazole [AS]

albendazole 400 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
15560Y	1	2	0.00	665.21	25.00	[a] Albendazole (Micro Labs, Germany) [DZ]

EVOLOCUMAB

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

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

19418

Familial homozygous hypercholesterolaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in conjunction with dietary therapy and exercise.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

evolocumab 140 mg/mL injection, 1 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
15599B NP	6	5	0.00	*1257.84	25.00	Repatha [AN]

EVOLOCUMAB

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

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

19523

Non-familial hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran, **AND**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Authority Required (STREAMLINED)

19514

Familial heterozygous hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

evolocumab 140 mg/mL injection, 1 mL pen device

15592P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	0.00	*841.68	25.00	Repatha [AN]

SALBUTAMOL

Note Pharmaceutical benefits that have the brand PMS-SALBUTAMOL (Canada) may be substituted for pharmaceutical benefits that have the brand Ventolin Nebules in the case of a shortage

Restricted benefit

Asthma

Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

11130T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	3	5	0.00	*32.25	25.00	[a] Ventolin Nebules [GK]

salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

13821K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	3	5	0.00	*151.65	25.00	[a] PMS-SALBUTAMOL (Canada) [RQ]

Highly Specialised Drugs Program (Private Hospital)

ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission:

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

Severe active juvenile idiopathic arthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2026, **AND**
- Patient must have, prior to initiating treatment with this drug for this condition, demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have, prior to initiating treatment with this drug for this condition, demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age, prior to commencement of this drug for this condition.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15597X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
2	5	0.00	*576.74	[a]	Amgevita [AN]

ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission:

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

Authority Required (STREAMLINED)

17713

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15585G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*576.74	[a] Amgevita [AN]

ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission:

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority Required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority Required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate

episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15556R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	0	0.00	*576.74	[a] Amgevita [AN]

CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

19424

Management of transplant rejection

Clinical criteria:

- The treatment must be used by organ or tissue transplant recipients.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

ciclosporin 50 mg/mL injection, 10 x 1 mL ampoules

6109M

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	67.34	Sandimmun [NV]

CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

19511

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

ciclosporin 10 mg capsule, 60

15622F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*87.64	Neoral 10 [NV]

ciclosporin 25 mg capsule, 30

15666M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	0.00	*101.40	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 25 [NV]	

ciclosporin 50 mg capsule, 30

15634W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	0.00	*200.04	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 50 [NV]	

ciclosporin 100 mg capsule, 30

15663J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	0.00	*398.00	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 100 [NV]	

ciclosporin 100 mg/mL oral liquid, 50 mL

15623G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	4	5	0.00	*1312.40	Neoral [NV]

CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

9695

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Treatment criteria:

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist.

Clinical criteria:

- The condition must be ineffective to other systemic therapies; **OR**
- The condition must be inappropriate for other systemic therapies.

Authority Required (STREAMLINED)

15361

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must be ineffective to other systemic therapies; **OR**
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; **OR**
- Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar.

For patients who do not demonstrate an adequate response to ciclosporin, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.

This assessment must be documented in the patient's medical records.

Authority Required (STREAMLINED)

9694

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have failed prior treatment with steroids and cytostatic drugs; **OR**
- Patient must be intolerant to treatment with steroids and cytostatic drugs; **OR**
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

Treatment criteria:

- Must be treated by a nephrologist.

Authority Required (STREAMLINED)

19423

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); **OR**
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist.

ciclosporin 10 mg capsule, 60

6232B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*87.64	Neoral 10 [NV]

ciclosporin 25 mg capsule, 30

6352H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	0.00	*101.40	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 25 [NV]	

ciclosporin 50 mg capsule, 30

6353J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	0.00	*200.04	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 50 [NV]	

ciclosporin 100 mg capsule, 30

6354K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	0.00	*398.00	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 100 [NV]	

ciclosporin 100 mg/mL oral liquid, 50 mL

6125J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	4	5	0.00	*1312.40	Neoral [NV]

DEFERASIROX

Authority Required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

Note A patient's median life expectancy is determined by the severity of their underlying disease.

Note Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:

- low risk according to the International Prognostic Scoring System (IPSS); or

- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

Note Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:
- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

deferasirox 90 mg tablet, 30

11558H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	2	0.00	*100.32	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 180 mg tablet, 30

11557G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	2	0.00	*190.32	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 360 mg tablet, 30

11511W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	2	0.00	*371.40	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox FCT MSN [VM]	[a] Deferasirox Sandoz [SZ]
					[a] DEFERASIROX-TEVA [TB]	[a] Eferas [AF]
					[a] Jadenu [NM]	[a] Pharmacor Deferasirox FC [CR]

DEFERASIROX

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

Authority Required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

Note A patient's median life expectancy is determined by the severity of their underlying disease.

Note Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:
- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

Note Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:
- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

deferasirox 125 mg dispersible tablet, 28

11241P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	6	2	0.00	*626.70	Deferasirox Juno [JU]

deferasirox 250 mg dispersible tablet, 28

11244T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	6	2	0.00	*137.64	Deferasirox Juno [JU]

deferasirox 500 mg dispersible tablet, 28

11232E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	2	0.00	*381.66	[a] Deferasirox Juno [JU]	[a] Pharmacor Deferasirox [CR]

DEFERASIROX

Authority Required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

Authority Required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

deferasirox 90 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11545P NP	6	5	0.00	*100.32	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 180 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11546Q NP	6	5	0.00	*190.32	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 360 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11496C NP	6	5	0.00	*371.40	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox FCT MSN [VM]	[a] Deferasirox Sandoz [SZ]
					[a] DEFERASIROX-TEVA [TB]	[a] Eferas [AF]
					[a] Jadenu [NM]	[a] Pharmacor Deferasirox FC [CR]

DEFERASIROX

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

Authority Required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

Authority Required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

deferasirox 125 mg dispersible tablet, 28

6499C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	6	5	0.00	*626.70	Deferasirox Juno [JU]

deferasirox 250 mg dispersible tablet, 28

6500D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	6	5	0.00	*137.64	Deferasirox Juno [JU]

deferasirox 500 mg dispersible tablet, 28

9600G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	5	0.00	*381.66	[a] Deferasirox Juno [JU]	[a] Pharmacor Deferasirox [CR]

DEFERASIROX

Authority Required (STREAMLINED)

19439

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

Authority Required (STREAMLINED)

19506

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

Authority Required (STREAMLINED)

19375

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a malignant disorder of haemopoieisis, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

Note Interruption of treatment should be considered if serum ferritin levels fall consistently below 500 microgram/mL.

deferasirox 90 mg tablet, 30

11548T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	2	0.00	*100.32	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 125 mg dispersible tablet, 28

11236J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	6	2	0.00	*626.70	Deferasirox Juno [JU]

deferasirox 180 mg tablet, 30

11510T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	2	0.00	*190.32	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]

11510T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 250 mg dispersible tablet, 28

11238L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	6	2	0.00	*137.64	Deferasirox Juno [JU]

deferasirox 360 mg tablet, 30

11547R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	2	0.00	*371.40	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox FCT MSN [VM]	[a] Deferasirox Sandoz [SZ]
					[a] DEFERASIROX-TEVA [TB]	[a] Eferas [AF]
					[a] Jadenu [NM]	[a] Pharmacor Deferasirox FC [CR]

deferasirox 500 mg dispersible tablet, 28

11243R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	2	0.00	*381.66	[a] Deferasirox Juno [JU]	[a] Pharmacor Deferasirox [CR]

DEFERIPRONE

Authority Required (STREAMLINED)

19437

Iron overload

Clinical criteria:

- Patient must have thalassaemia major, **AND**
- Patient must be unable to take desferrioxamine therapy.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

Authority Required (STREAMLINED)

19492

Iron overload

Clinical criteria:

- Patient must have thalassaemia major, **AND**
- Patient must be one in whom desferrioxamine therapy has proven ineffective.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

deferiprone 100 mg/mL oral liquid, 250 mL

9638G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	5	5	0.00	*1010.84	Ferriprox [EU]

deferiprone 500 mg tablet, 100

6416Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	3	5	0.00	*1204.92	Ferriprox [EU]

deferiprone 1 g tablet, 50

11724C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	6	5	0.00	*2360.64	Ferriprox [EU]

DESFERRIOXAMINE

Authority Required (STREAMLINED)

19477

Disorders of erythropoiesis

Clinical criteria:

- The condition must be associated with treatment-related chronic iron overload.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

desferrioxamine mesilate 500 mg injection, 10 vials

6113R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	40	5	0.00	*5604.44	DBL Desferrioxamine Mesilate [PF]

desferrioxamine mesilate 2 g injection, 1 vial

6270B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	60	5	0.00	*2664.24	DBL Desferrioxamine Mesilate [PF]

DORNASE ALFA

Authority Required (STREAMLINED)

19554

Cystic fibrosis

Population criteria:

- Patient must be 5 years of age or older.

Clinical criteria:

- Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority Required (STREAMLINED)

19559

Cystic fibrosis

Clinical criteria:

- Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; **OR**
- Patient must have significant bronchiectasis on chest high resolution computed tomography scan; **OR**
- Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; **OR**
- Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy, **AND**
- Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Population criteria:

- Patient must be less than 5 years of age.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority Required (STREAMLINED)

19378

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have initiated treatment with dornase alfa at an age of less than 5 years, **AND**
- Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

Population criteria:

- Patient must be 5 years of age or older.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

6120D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*1540.22	Pulmozyme [RO]

ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one mutation in the CFTR gene that is considered responsive to elexacaftor/tezacaftor/ivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be aged between 2 and 11 years inclusive.

For the purposes of this restriction, the list of mutations considered to be responsive to elexacaftor/tezacaftor/ivacaftor is defined in the TGA approved Product Information (PI). Mutations that are not listed in the TGA approved PI but considered to be responsive to elexacaftor/tezacaftor/ivacaftor can be accepted with a confirmation that these patients do not harbour two Class I mutations.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating the specific mutation considered to be responsive to elexacaftor/tezacaftor/ivacaftor as listed in the TGA approved PI - quote each of the: (i) specific mutation, and if the specific mutation is not listed in the TGA approved PI, confirmation that the patient does not harbour two Class I mutations, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg granules [28] (&) ivacaftor 75 mg granules [28], 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14280N	1	5	0.00	20355.49	Trikafta [VR]

ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be aged between 2 and 11 years inclusive.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

elexacaftor 50 mg + tezacaftor 25 mg + ivacaftor 37.5 mg tablet [56] (&) ivacaftor 75 mg tablet [28], 84

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15620D NP	1	5	0.00	20355.49	Trikafta [VR]

elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg granules [28] (&) ivacaftor 75 mg granules [28], 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15671T NP	1	5	0.00	20355.49	Trikafta [VR]

ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be at least 6 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84

15646L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20355.49	Trikafta [VR]

ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 2 to 5 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

elexacaftor 80 mg + tezacaftor 40 mg + ivacaftor 60 mg granules [28] (&) ivacaftor 59.5 mg granules [28], 56

15656B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20355.49	Trikafta [VR]

EVEROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

19370

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19459

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

everolimus 250 microgram tablet, 60

6459Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*325.26	[a] Certican [NV]	[a] Everocan [CR]

everolimus 500 microgram tablet, 60

6460B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*560.88	[a] Certican [NV]	[a] Everocan [CR]

everolimus 750 microgram tablet, 60

6461C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	0.00	*1640.48	[a] Certican [NV]	[a] Everocan [CR]

everolimus 1 mg tablet, 60

9582H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	0.00	*2170.92	[a] Certican [NV]	[a] Everocan [CR]

FILGRASTIM

Authority Required (STREAMLINED)

19398

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19447

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19339

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19333

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19399

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**

- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19334

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19395

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19400

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; **OR**
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19330

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes

5830W

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	11	0.00	*266.82	Nivestim [PF]

FILGRASTIM

Note Pharmaceutical benefits that have the forms filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)

19398

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19447

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19339

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19333

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19399

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19334

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19395

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19400

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; **OR**
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19330

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2733W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	4	11	0.00	*400.92	[a] Zarzio [SZ]

filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

6292E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	11	0.00	*400.90	[a] Nivestim [PF]

FILGRASTIM

Note Pharmaceutical benefits that have the forms filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)

19398

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**

- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19447

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19339

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19333

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19399

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19334

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19395

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19400

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; **OR**
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19330

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2747N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	11	0.00	*253.56	[a] Zarzio [SZ]

NP

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

6291D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	0.00	*253.56	[a] Nivestim [PF]

NP

IVACAFTOR

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Continuing treatment (gating mutations)

Clinical criteria:

- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit.

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis.

Population criteria:

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ivacaftor 25 mg granules, 56 sachets

15613R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20355.49	Kalydeco [VR]

ivacaftor 50 mg granules, 56 sachets

15680G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20355.49	Kalydeco [VR]

ivacaftor 75 mg granules, 56 sachets

15650Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20355.49	Kalydeco [VR]

ivacaftor 150 mg tablet, 56

15631Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20355.49	Kalydeco [VR]

IVACAFTOR

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Continuing treatment (non-gating mutations)

Clinical criteria:

- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit.

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis.

Population criteria:

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ivacaftor 25 mg granules, 56 sachets

15614T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20355.49	Kalydeco [VR]

ivacaftor 50 mg granules, 56 sachets

15662H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20355.49	Kalydeco [VR]

ivacaftor 75 mg granules, 56 sachets

15660F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20355.49	Kalydeco [VR]

ivacaftor 150 mg tablet, 56

15621E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20355.49	Kalydeco [VR]

LANREOTIDE

Note Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Authority Required (STREAMLINED)

19552

Functional carcinoid tumour

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe

15678E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*1748.70	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe

15608L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*2310.98	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

15637B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*2630.76	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

LANREOTIDE

Note Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

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

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

Authority Required (STREAMLINED)

19542

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

Clinical criteria:

- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be either: (i) as monotherapy; (ii) in combination with cabozantinib.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

11527Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*2630.76	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

LUMACAFTOR + IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be at least 1 year of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 75 mg + ivacaftor 94 mg granules, 56 sachets

15643H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	‡1	5	0.00	16971.12	Orkambi [VR]

lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets

15633T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	‡1	5	0.00	16971.12	Orkambi [VR]

lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets

15664K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	‡1	5	0.00	16971.12	Orkambi [VR]

LUMACAFTOR + IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be at least 12 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 200 mg + ivacaftor 125 mg tablet, 112

15653W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	16971.12	Orkambi [VR]

NP

LUMACAFTOR + IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged between 6 and 11 years inclusive.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 100 mg + ivacaftor 125 mg tablet, 112

15676C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	16971.12	Orkambi [VR]

NP

MANNITOL

Authority Required (STREAMLINED)

19472

Cystic fibrosis

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must be intolerant or inadequately responsive to dornase alfa.

Population criteria:

- Patient must be 6 years of age or older.

Treatment criteria:

- Must be treated in a cystic fibrosis clinic/centre where there are specialist respiratory physicians with expertise in the management of cystic fibrosis; **OR**
- Must be treated by a specialist physician in consultation with the above mentioned specialist medical practitioner(s); **OR**
- Must be treated by a paediatrician in consultation with a specialist respiratory physician; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis.

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority Required (STREAMLINED)

19379

Cystic fibrosis

Clinical criteria:

- The treatment must be in combination with dornase alfa, **AND**
- Patient must be inadequately responsive to dornase alfa, **AND**
- Patient must have trialled hypertonic saline for this condition.

Population criteria:

- Patient must be 6 years of age or older.

Treatment criteria:

- Must be treated in a cystic fibrosis clinic/centre where there are specialist respiratory physicians with expertise in the management of cystic fibrosis; **OR**
- Must be treated by a specialist physician in consultation with the above mentioned specialist medical practitioner(s); **OR**
- Must be treated by a paediatrician in consultation with a specialist respiratory physician; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis.

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

mannitol 40 mg powder for inhalation, 280 capsules

2008Q

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	4	5	0.00	*1838.44	Bronchitol [HT]

MEPOLIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority Required

Uncontrolled chronic obstructive pulmonary disease (COPD)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this biological medicine for this condition, **AND**

- Patient must have both, achieved and sustained an adequate response to this drug, compared to the baseline levels provided with the initial PBS authority application, **AND**
- The treatment must be in combination with all of: (i) LAMA; (ii) LABA; (iii) ICS in an optimised triple inhaler therapy, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician; (ii) general physician experienced in the management of patients with this condition.

Assessment of adequate response for continuing treatment:

For patients with severe exacerbations at baseline, adequate response is defined as:

- Maintenance (i.e. no change) or a reduction in the number of severe exacerbations compared with baseline; and
- No increase in the total number of moderate and severe exacerbations.

For patients with moderate exacerbations only at baseline, adequate response is defined as:

- Maintenance (i.e. no change) or a reduction in the number of moderate exacerbations compared with baseline; and
- No occurrence of a severe exacerbation.

The following must be provided in each continuing PBS authority application and be documented in the patient's medical records:

details of the current number and severity of exacerbations compared to baseline levels provided in the initial authority application of this treatment cycle including:

(i) number of moderate exacerbations requiring treatment with systemic corticosteroids; and/or

(ii) number of moderate exacerbations requiring treatment with antibiotics; and

(iii) number of severe exacerbation(s) which required hospitalisation.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

Uncontrolled chronic obstructive pulmonary disease (COPD)

Treatment Phase: Grandfather arrangements - Transitioning from non-PBS to PBS-subsidised supply

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 September 2026, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre in the 12 months prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have achieved, prior to commencing non-PBS-subsidised treatment with this drug for this condition, adequate control with at least 3 months of optimised triple inhaled therapy consisting of: (i) long-acting muscarinic antagonist (LAMA); (ii) a long-acting beta-2 agonist (LABA); (iii) an inhaled corticosteroid (ICS), despite formal assessment of and adherence to correct inhaler technique which has been documented in the patient's medical records, **AND**
- Patient must have experienced at least one severe COPD exacerbation, or at least two moderate COPD exacerbations in the 12 months prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with all of: (i) LAMA; (ii) LABA; (iii) ICS in an optimised triple inhaler therapy, **AND**
- Patient must have both, achieved and sustained an adequate response to this drug, defined as maintenance (i.e. no change); or a reduction in the number of moderate and/or severe exacerbation(s) compared to the baseline levels provided with this authority application, if they received at least 24 weeks of treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician; (ii) general physician experienced in the management of patients with this condition.

For the purpose of administering this restriction, COPD exacerbations in the 12 months prior to commencing non-PBS-subsidised treatment with this drug for this condition, are defined as experiencing:

(i) at least 1 severe COPD exacerbation which required hospitalisation; and/or

(ii) 2 or more moderate COPD exacerbations, of which at least:

(a) one required treatment with systemic corticosteroids; and

(b) one required treatment with systemic corticosteroids or antibiotics.

At least one of the moderate or severe exacerbations must have occurred while the patient was taking all of: (i) LAMA; (ii) LABA; and (iii) ICS in an optimised triple inhaler therapy.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include the following:

(i) the blood eosinophil count and date; AND

(ii) details of therapy with a combination of LAMA, LABA and ICS (name of treatment, dosage, date of commencement, and duration of therapy prior to commencing non-PBS-subsidised treatment with this drug for this condition); AND

(iii) the baseline exacerbation history which includes:

details of the number and severity of COPD exacerbations experienced in the 12 months immediately prior to commencement of this drug as non-PBS-subsidised therapy for this condition, including:

(a) number of moderate exacerbations requiring treatment with systemic corticosteroids; and/or

(b) number of moderate exacerbations requiring treatment with antibiotics; and

(c) number of severe exacerbations requiring hospitalisation; AND

(iv) the assessment of response to treatment where applicable (for patients who have received at least 24 weeks of treatment), which includes:

details of the current number and severity of COPD exacerbations, compared with the baseline information supplied in this authority application, including:

(a) number of moderate exacerbations requiring treatment with systemic corticosteroids; and/or

(b) number of moderate exacerbations requiring treatment with antibiotics; and

(c) number of severe exacerbations requiring hospitalisation.

The details of the number and the severity of COPD exacerbations are to inform the basis of determining if an adequate response to treatment has been achieved under the continuing treatment restriction.

In addition to stating the above details in the authority application, document them in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

mepolizumab 100 mg/mL injection, 1 mL pen device

15508F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1605.34	Nucala [GK]

MIDOSTAURIN

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

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

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

Acute Myeloid Leukaemia

Treatment Phase: Maintenance therapy - Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial maintenance treatment restriction, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

A maximum of 9 cycles will be authorised under this restriction in a lifetime.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;

- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

midostaurin 25 mg capsule, 112

11518F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	2	0.00	18471.98	Rydapt [NV]

MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

19362

Prophylaxis of renal allograft rejection

Treatment Phase: Management

Clinical criteria:

- The treatment must be under the supervision and direction of a transplant unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Note Management includes initiation, stabilisation and review of therapy as required.

mycophenolate 180 mg enteric tablet, 120

15673X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*156.80	[a] Mycophenolic Acid ARX [XT]	[a] Myfortic [NV]

mycophenolate 360 mg enteric tablet, 120

15674Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*280.82	[a] Mycophenolic Acid ARX [XT]	[a] MYCOTEX [CR]
					[a] Myfortic [NV]	

MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

19370

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19459

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

mycophenolate mofetil 250 mg capsule, 100

6208R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	5	0.00	*129.06	[a] APO-Mycophenolate [TX]	[a] Mycophenolate Sandoz [SZ]

6208R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
					[a] Pharmacor Mycophenolate 250 [CR]	

mycophenolate mofetil 500 mg tablet, 50

6209T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	5	0.00	*128.94	[a] ARX-MYCOPHENOLATE [XT]	[a] Ceptolate [AF]
					[a] Mycophenolate GH [GQ]	[a] Mycophenolate Sandoz [SZ]
					[a] Pharmacor Mycophenolate 500 [CR]	

mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL

6364Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*399.57	[a] CellCept [RO]	[a] Pharmacor Mycophenolate [CR]

OCTREOTIDE

Authority Required (STREAMLINED)

19442

Functional carcinoid tumour

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority Required (STREAMLINED)

19321

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 50 microgram/mL injection, 5 x 1 mL ampoules

15628M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	18	11	0.00	*271.32	[a] Octreotide GH [HQ]	[a] Octreotide (SUN) [RA]
					[a] Sandostatin 0.05 [NV]	

octreotide 100 microgram/mL injection, 5 x 1 mL ampoules

15610N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	18	11	0.00	*533.40	[a] Octreotide GH [HQ]	[a] Octreotide (SUN) [RA]
					[a] Sandostatin 0.1 [NV]	

octreotide 500 microgram/mL injection, 5 x 1 mL ampoules

15648N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	18	11	0.00	*1919.58	[a] Octreotide GH [HQ]	[a] Octreotide (SUN) [RA]
					[a] Sandostatin 0.5 [NV]	

OCTREOTIDE

Authority Required (STREAMLINED)

19543

Functional carcinoid tumour

Clinical criteria:

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Treatment criteria:

- Must be treated by a medical practitioner where the prescription continues existing therapy with this medicine; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority Required (STREAMLINED)

19544

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Treatment criteria:

- Must be treated by a medical practitioner where the prescription continues existing therapy with this medicine; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

15629N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*829.96	Sandostatin LAR [NV]

NP

octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

15649P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*1099.86	Sandostatin LAR [NV]

NP

octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

15639D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*1256.56	Sandostatin LAR [NV]

NP

OCTREOTIDE

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

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

Authority Required (STREAMLINED)

19538

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

Clinical criteria:

- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be either: (i) as monotherapy; (ii) in combination with cabozantinib.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a medical practitioner where the prescription continues existing therapy with this medicine; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

11894B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*1256.56	Sandostatin LAR [NV]

NP

PEGFILGRASTIM

Authority Required (STREAMLINED)

19449

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19508

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

6363X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	11	0.00	90.76	[a] Pelgraz [OC]	[a] Ziextenzo [SZ]

SIROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

19370

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

sirolimus 500 microgram tablet, 100

9748C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*620.28	Rapamune [PF]

sirolimus 1 mg tablet, 100

6436R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*1224.28	Rapamune [PF]

sirolimus 1 mg/mL oral liquid, 60 mL

6437T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*970.22	Rapamune [PF]

sirolimus 2 mg tablet, 100

6457W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*2399.36	Rapamune [PF]

TACROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

19314

Management of rejection in patients following organ or tissue transplantation

Clinical criteria:

- The treatment must be under the supervision and direction of a transplant unit, **AND**
- The treatment must include initiation, stabilisation, and review of therapy as required.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

tacrolimus 500 microgram capsule, 100

6328C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*121.56	[a] Pacrolim [AF]	[a] Pharmacor Tacrolimus 0.5 [CR]
					[a] Prograf [LL]	[a] Tacrograf [RW]
					[a] Tacrolimus Sandoz [SZ]	

tacrolimus 500 microgram modified release capsule, 30

9681M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*88.28	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 750 microgram capsule, 100

10875J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*179.94	Tacrolimus Sandoz [SZ]

tacrolimus 1 mg capsule, 100

6216E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*231.80	[a] Pacrolim [AF]	[a] Pharmacor Tacrolimus 1 [CR]
					[a] Prograf [LL]	[a] Tacrograf [RW]
					[a] Tacrolimus Sandoz [SZ]	

tacrolimus 1 mg modified release capsule, 60

9682N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*140.28	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 2 mg capsule, 100

10879N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*497.32	Tacrolimus Sandoz [SZ]

tacrolimus 3 mg modified release capsule, 50

11920J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	0.00	*725.80	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 5 mg capsule, 50

6217F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*555.10	[a] Pharmacor Tacrolimus 5 [CR]	[a] Prograf [LL]
					[a] Tacrograf [RW]	[a] Tacrolimus Sandoz [SZ]

tacrolimus 5 mg modified release capsule, 30

9683P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*820.44	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

TEPROTUMUMAB

Caution Teprotumumab is contraindicated in pregnancy. Women of childbearing potential should have a negative pregnancy test before starting treatment with teprotumumab, and monthly during treatment and for 6 months after cessation of treatment. If the patient becomes pregnant during treatment, teprotumumab should be discontinued. See also TGA approved Product Information.

Caution Assess patient's hearing before, and routinely during and after treatment, including use of audiograms where clinically warranted.
If significant hearing loss is experienced while receiving treatment with this drug for this condition, treatment discontinuation is advised. See also TGA approved Product Information.

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

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

19461

Active moderate to severe thyroid eye disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the management of thyroid eye disease; or in consultation with a specialist medical practitioner experienced in the management of thyroid eye disease.

Increased quantities may only be authorised where a patient's weight is greater than 150 kg.

After completing 8 doses in total of PBS-subsidised treatment with teprotumumab, a patient may be eligible for re-treatment through the initial treatment phase only, if a response to treatment was previously demonstrated.

Teprotumumab 500 mg injection, 1 vial

15605H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6	6	0.00	*63935.34	Tepezza [AN]

TEPROTUMUMAB

Caution Teprotumumab is contraindicated in pregnancy. Women of childbearing potential should have a negative pregnancy test before starting treatment with teprotumumab, and monthly during treatment and for 6 months after cessation of treatment. If the patient becomes pregnant during treatment, teprotumumab should be discontinued. See also TGA approved Product Information.

Caution Assess patient's hearing before, and routinely during and after treatment, including use of audiograms where clinically warranted.
If significant hearing loss is experienced while receiving treatment with this drug for this condition, treatment discontinuation is advised. See also TGA approved Product Information.

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

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

Note Special Pricing Arrangements apply.

Authority Required

Active moderate to severe thyroid eye disease

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be both: (i) undergoing re-treatment with this drug for this condition; and (ii) have demonstrated response to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a clinical activity score (CAS) of at least three for the most severely affected eye, **AND**
- Patient must have two or more of the following: (i) Proptosis at least 3 mm above normal for race and gender; (ii) Lid retraction of at least 2 mm; (iii) Moderate to severe soft-tissue involvement; (iv) Inconstant or constant diplopia.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the treatment of thyroid eye disease.

The following must be provided at the time of application and documented in the patient's medical records for the first prescription only:

(1) Baseline clinical activity score (CAS); and

(2) Confirmation of the presence of thyroid eye disease.

This includes evidence of two or more of the following:

(i) Proptosis at least 3 mm above normal for race and gender;

(ii) Lid retraction of at least 2 mm;

(iii) Moderate to severe soft-tissue involvement;

(iv) Inconstant or constant diplopia.

Increased quantities may only be authorised where a patient's weight is greater than 150 kg.

After completing 8 doses in total of PBS-subsidised treatment with teprotumumab, a patient may be eligible for re-treatment through the initial treatment phase only, if a response to treatment was previously demonstrated.

Teprotumumab 500 mg injection, 1 vial

15568J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	0	0.00	*31992.27	Tepezza [AN]

TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be at least 12 years of age.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56

15606J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	19001.74	Symdeko [VR]

TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be at least 12 years of age.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56

15635X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	19001.74	Symdeko [VR]

VALGANCICLOVIR

Authority Required (STREAMLINED)

19505

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19463

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

valganciclovir 50 mg/mL powder for oral liquid, 100 mL

9675F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	11	5	0.00	*4398.63	Valcyte [PB]

valganciclovir 450 mg tablet, 60

6357N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*504.50	[a] Valganciclovir Sandoz [SZ]	[a] Valganciclovir Viatris [AL]

ZOLEDRONIC ACID

Authority Required (STREAMLINED)

19289

Adjuvant management of breast cancer

Population criteria:

- Patient must be post-menopausal.

Treatment criteria:

- Patient must not be undergoing PBS-subsidised treatment with this drug for this indication for more than 36 months, **AND**
- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

zoledronic acid 4 mg/5 mL injection, 5 mL vial

13772W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	0	0.00	58.96	[a] DEZTRON [DZ]	[a] Zoledronate-DRLA 4 [RZ]
					[a] Zoledronic Acid Accord [OC]	

Highly Specialised Drugs Program (Public Hospital)

ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission:

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

Severe active juvenile idiopathic arthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2026, **AND**
- Patient must have, prior to initiating treatment with this drug for this condition, demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have, prior to initiating treatment with this drug for this condition, demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age, prior to commencement of this drug for this condition.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
15571M	2	5	0.00	*545.68	[a]	Amgevita [AN]

ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission:

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

Authority Required (STREAMLINED)

17707

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15549J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*545.68	[a] Amgevita [AN]

ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission:

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority Required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority Required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate

episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15555Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	0	0.00	*545.68	[a] Amgevita [AN]

CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

19503

Management of transplant rejection

Clinical criteria:

- The treatment must be used by organ or tissue transplant recipients.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

ciclosporin 50 mg/mL injection, 10 x 1 mL ampoules

5631J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	54.10	Sandimmun [NV]

NP

CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

19414

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

ciclosporin 10 mg capsule, 60

15632R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*74.40	Neoral 10 [NV]

ciclosporin 25 mg capsule, 30

15665L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	0.00	*88.16	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 25 [NV]	

ciclosporin 50 mg capsule, 30

15642G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	0.00	*183.48	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 50 [NV]	

ciclosporin 100 mg capsule, 30

15677D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	0.00	*373.80	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 100 [NV]	

ciclosporin 100 mg/mL oral liquid, 50 mL

15654X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	4	5	0.00	*1263.16	Neoral [NV]

CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

6660

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Treatment criteria:

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist.

Clinical criteria:

- The condition must be ineffective to other systemic therapies; **OR**
- The condition must be inappropriate for other systemic therapies.

Authority Required (STREAMLINED)

15360

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must be ineffective to other systemic therapies; **OR**
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; **OR**
- Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar.

For patients who do not demonstrate an adequate response to ciclosporin, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.

This assessment must be documented in the patient's medical records.

Authority Required (STREAMLINED)

6631

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have failed prior treatment with steroids and cytostatic drugs; **OR**
- Patient must be intolerant to treatment with steroids and cytostatic drugs; **OR**
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

Treatment criteria:

- Must be treated by a nephrologist.

Authority Required (STREAMLINED)

19482

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); **OR**
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist.

ciclosporin 10 mg capsule, 60

5632K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*74.40	Neoral 10 [NV]

ciclosporin 25 mg capsule, 30

5634M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	0.00	*88.16	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 25 [NV]	

ciclosporin 50 mg capsule, 30

5635N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	0.00	*183.48	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 50 [NV]	

ciclosporin 100 mg capsule, 30

5636P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	0.00	*373.80	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 100 [NV]	

ciclosporin 100 mg/mL oral liquid, 50 mL

5633L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	4	5	0.00	*1263.16	Neoral [NV]

DEFERASIROX

Authority Required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

Note A patient's median life expectancy is determined by the severity of their underlying disease.

Note Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:

- low risk according to the International Prognostic Scoring System (IPSS); or

- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

Note Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:
- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

deferasirox 90 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11519G NP	6	2	0.00	*87.06	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 180 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11500G NP	6	2	0.00	*174.12	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 360 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11536E NP	6	2	0.00	*348.24	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox FCT MSN [VM]	[a] Deferasirox Sandoz [SZ]
					[a] DEFERASIROX-TEVA [TB]	[a] Eferas [AF]
					[a] Jadenu [NM]	[a] Pharmacor Deferasirox FC [CR]

DEFERASIROX

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

Authority Required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

Note A patient's median life expectancy is determined by the severity of their underlying disease.

Note Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:
- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

Note Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:
- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

deferasirox 125 mg dispersible tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11235H NP	6	2	0.00	*593.70	Deferasirox Juno [JU]

deferasirox 250 mg dispersible tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11239M NP	6	2	0.00	*123.48	Deferasirox Juno [JU]

deferasirox 500 mg dispersible tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11231D NP	6	2	0.00	*358.08	[a] Deferasirox Juno [JU]	[a] Pharmacor Deferasirox [CR]

DEFERASIROX

Authority Required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

Authority Required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

deferasirox 90 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11499F NP	6	5	0.00	*87.06	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 180 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11556F NP	6	5	0.00	*174.12	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 360 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11533B NP	6	5	0.00	*348.24	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox FCT MSN [VM]	[a] Deferasirox Sandoz [SZ]
					[a] DEFERASIROX-TEVA [TB]	[a] Eferas [AF]
					[a] Jadenu [NM]	[a] Pharmacor Deferasirox FC [CR]

DEFERASIROX

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

Authority Required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

Authority Required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

deferasirox 125 mg dispersible tablet, 28

11247Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	6	5	0.00	*593.70	Deferasirox Juno [JU]

deferasirox 250 mg dispersible tablet, 28

11240N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	6	5	0.00	*123.48	Deferasirox Juno [JU]

deferasirox 500 mg dispersible tablet, 28

11234G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	5	0.00	*358.08	[a] Deferasirox Juno [JU]	[a] Pharmacor Deferasirox [CR]

DEFERASIROX

Authority Required (STREAMLINED)

19386

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

Authority Required (STREAMLINED)

19384

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

Authority Required (STREAMLINED)

19311

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a malignant disorder of haemopoieisis, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

Note Interruption of treatment should be considered if serum ferritin levels fall consistently below 500 microgram/mL.

deferasirox 90 mg tablet, 30

11534C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	2	0.00	*87.06	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 125 mg dispersible tablet, 28

5654N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	6	2	0.00	*593.70	Deferasirox Juno [JU]

deferasirox 180 mg tablet, 30

11535D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	2	0.00	*174.12	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]

11535D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 250 mg dispersible tablet, 28

5655P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	6	2	0.00	*123.48	Deferasirox Juno [JU]

deferasirox 360 mg tablet, 30

11555E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	2	0.00	*348.24	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox FCT MSN [VM]	[a] Deferasirox Sandoz [SZ]
					[a] DEFERASIROX-TEVA [TB]	[a] Eferas [AF]
					[a] Jadenu [NM]	[a] Pharmacor Deferasirox FC [CR]

deferasirox 500 mg dispersible tablet, 28

5656Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	2	0.00	*358.08	[a] Deferasirox Juno [JU]	[a] Pharmacor Deferasirox [CR]

DEFERIPRONE

Authority Required (STREAMLINED)

19310

Iron overload

Clinical criteria:

- Patient must have thalassaemia major, **AND**
- Patient must be unable to take desferrioxamine therapy.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

Authority Required (STREAMLINED)

19436

Iron overload

Clinical criteria:

- Patient must have thalassaemia major, **AND**
- Patient must be one in whom desferrioxamine therapy has proven ineffective.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

deferiprone 100 mg/mL oral liquid, 250 mL

5658T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	5	5	0.00	*963.10	Ferriprox [EU]

deferiprone 500 mg tablet, 100

5657R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	3	5	0.00	*1155.69	Ferriprox [EU]

deferiprone 1 g tablet, 50

11747G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	6	5	0.00	*2311.38	Ferriprox [EU]

DESFERRIOXAMINE

Authority Required (STREAMLINED)

19476

Disorders of erythropoiesis

Clinical criteria:

- The condition must be associated with treatment-related chronic iron overload.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

desferrioxamine mesilate 500 mg injection, 10 vials

5662B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	40	5	0.00	*5555.20	DBL Desferrioxamine Mesilate [PF]

desferrioxamine mesilate 2 g injection, 1 vial

5661Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	60	5	0.00	*2614.80	DBL Desferrioxamine Mesilate [PF]

DORNASE ALFA

Authority Required (STREAMLINED)

19563

Cystic fibrosis

Population criteria:

- Patient must be 5 years of age or older.

Clinical criteria:

- Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority Required (STREAMLINED)

19546

Cystic fibrosis

Clinical criteria:

- Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; **OR**
- Patient must have significant bronchiectasis on chest high resolution computed tomography scan; **OR**
- Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; **OR**
- Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy, **AND**
- Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Population criteria:

- Patient must be less than 5 years of age.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority Required (STREAMLINED)

19432

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have initiated treatment with dornase alfa at an age of less than 5 years, **AND**
- Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

Population criteria:

- Patient must be 5 years of age or older.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

5704F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*1490.98	Pulmozyme [RO]

ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one mutation in the CFTR gene that is considered responsive to elexacaftor/tezacaftor/ivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be aged between 2 and 11 years inclusive.

For the purposes of this restriction, the list of mutations considered to be responsive to elexacaftor/tezacaftor/ivacaftor is defined in the TGA approved Product Information (PI). Mutations that are not listed in the TGA approved PI but considered to be responsive to elexacaftor/tezacaftor/ivacaftor can be accepted with a confirmation that these patients do not harbour two Class I mutations.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating the specific mutation considered to be responsive to elexacaftor/tezacaftor/ivacaftor as listed in the TGA approved PI - quote each of the: (i) specific mutation, and if the specific mutation is not listed in the TGA approved PI, confirmation that the patient does not harbour two Class I mutations, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg granules [28] (&) ivacaftor 75 mg granules [28], 56

14228W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	20306.25	Trikafta [VR]

ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be aged between 2 and 11 years inclusive.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

elexacaftor 50 mg + tezacaftor 25 mg + ivacaftor 37.5 mg tablet [56] (&) ivacaftor 75 mg tablet [28], 84

15611P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20306.25	Trikafta [VR]

elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg granules [28] (&) ivacaftor 75 mg granules [28], 56

15657C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20306.25	Trikafta [VR]

ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be at least 6 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84

15625J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20306.25	Trikafta [VR]

ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 2 to 5 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

elexacaftor 80 mg + tezacaftor 40 mg + ivacaftor 60 mg granules [28] (&) ivacaftor 59.5 mg granules [28], 56

15626K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20306.25	Trikafta [VR]

EVEROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

19365

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19366

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

everolimus 250 microgram tablet, 60

5738B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*303.86	[a] Certican [NV]	[a] Everocan [CR]

everolimus 500 microgram tablet, 60

5739C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*530.42	[a] Certican [NV]	[a] Everocan [CR]

everolimus 750 microgram tablet, 60

5740D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	0.00	*1591.24	[a] Certican [NV]	[a] Everocan [CR]

everolimus 1 mg tablet, 60

5737Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	0.00	*2121.68	[a] Certican [NV]	[a] Everocan [CR]

FILGRASTIM

Authority Required (STREAMLINED)

19332

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19403

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19392

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19325

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19443

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**

- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19340

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19326

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19397

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; **OR**
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19327

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes

5829T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	11	0.00	*247.68	Nivestim [PF]

FILGRASTIM

Note Pharmaceutical benefits that have the forms filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)

19332

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19403

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19392

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19325

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19443

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19340

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19326

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19397

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; **OR**
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19327

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2758E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	4	11	0.00	*234.92	[a] Zarzio [SZ]

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

5742F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	11	0.00	*234.92	[a] Nivestim [PF]

FILGRASTIM

Note Pharmaceutical benefits that have the forms filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)

19332

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**

- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19403

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19392

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19325

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19443

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19340

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19326

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19397

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; **OR**
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19327

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2783L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	11	0.00	*376.60	[a] Zarzio [SZ]

NP

filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

5744H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	0.00	*376.60	[a] Nivestim [PF]

NP

IVACAFTOR

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Continuing treatment (gating mutations)

Clinical criteria:

- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit.

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis.

Population criteria:

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ivacaftor 25 mg granules, 56 sachets

15616X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20306.25	Kalydeco [VR]

ivacaftor 50 mg granules, 56 sachets

15661G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20306.25	Kalydeco [VR]

ivacaftor 75 mg granules, 56 sachets

15675B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20306.25	Kalydeco [VR]

ivacaftor 150 mg tablet, 56

15612Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20306.25	Kalydeco [VR]

IVACAFTOR

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Continuing treatment (non-gating mutations)

Clinical criteria:

- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit.

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis.

Population criteria:

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ivacaftor 25 mg granules, 56 sachets

15615W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20306.25	Kalydeco [VR]

ivacaftor 50 mg granules, 56 sachets

15682J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20306.25	Kalydeco [VR]

ivacaftor 75 mg granules, 56 sachets

15640E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20306.25	Kalydeco [VR]

ivacaftor 150 mg tablet, 56

15630P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	20306.25	Kalydeco [VR]

LANREOTIDE

Note Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Authority Required (STREAMLINED)

19560

Functional carcinoid tumour

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe

15645K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*1699.46	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe

15624H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*2261.74	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

15607K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*2581.52	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

LANREOTIDE

Note Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

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

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

Authority Required (STREAMLINED)

19534

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

Clinical criteria:

- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be either: (i) as monotherapy; (ii) in combination with cabozantinib.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

11513Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*2581.52	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

LUMACAFTOR + IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged between 6 and 11 years inclusive.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 100 mg + ivacaftor 125 mg tablet, 112

15617Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	16921.88	Orkambi [VR]

LUMACAFTOR + IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be at least 12 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 200 mg + ivacaftor 125 mg tablet, 112

15618B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	16921.88	Orkambi [VR]

LUMACAFTOR + IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be at least 1 year of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 75 mg + ivacaftor 94 mg granules, 56 sachets

15644J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	‡1	5	0.00	16921.88	Orkambi [VR]

lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets

15641F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	‡1	5	0.00	16921.88	Orkambi [VR]

lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets

15652T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	‡1	5	0.00	16921.88	Orkambi [VR]

MANNITOL

Authority Required (STREAMLINED)

19292

Cystic fibrosis

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must be intolerant or inadequately responsive to dornase alfa.

Population criteria:

- Patient must be 6 years of age or older.

Treatment criteria:

- Must be treated in a cystic fibrosis clinic/centre where there are specialist respiratory physicians with expertise in the management of cystic fibrosis; **OR**
- Must be treated by a specialist physician in consultation with the above mentioned specialist medical practitioner(s); **OR**
- Must be treated by a paediatrician in consultation with a specialist respiratory physician; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis.

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority Required (STREAMLINED)

19380

Cystic fibrosis

Clinical criteria:

- The treatment must be in combination with dornase alfa, **AND**
- Patient must be inadequately responsive to dornase alfa, **AND**
- Patient must have trialled hypertonic saline for this condition.

Population criteria:

- Patient must be 6 years of age or older.

Treatment criteria:

- Must be treated in a cystic fibrosis clinic/centre where there are specialist respiratory physicians with expertise in the management of cystic fibrosis; **OR**
- Must be treated by a specialist physician in consultation with the above mentioned specialist medical practitioner(s); **OR**
- Must be treated by a paediatrician in consultation with a specialist respiratory physician; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis.

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

mannitol 40 mg powder for inhalation, 280 capsules

2015C

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	4	5	0.00	*1789.20	Bronchitol [HT]

MEPOLIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority Required

Uncontrolled chronic obstructive pulmonary disease (COPD)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this biological medicine for this condition, **AND**

- Patient must have both, achieved and sustained an adequate response to this drug, compared to the baseline levels provided with the initial PBS authority application, **AND**
- The treatment must be in combination with all of: (i) LAMA; (ii) LABA; (iii) ICS in an optimised triple inhaler therapy, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician; (ii) general physician experienced in the management of patients with this condition.

Assessment of adequate response for continuing treatment:

For patients with severe exacerbations at baseline, adequate response is defined as:

- Maintenance (i.e. no change) or a reduction in the number of severe exacerbations compared with baseline; and
- No increase in the total number of moderate and severe exacerbations.

For patients with moderate exacerbations only at baseline, adequate response is defined as:

- Maintenance (i.e. no change) or a reduction in the number of moderate exacerbations compared with baseline; and
- No occurrence of a severe exacerbation.

The following must be provided in each continuing PBS authority application and be documented in the patient's medical records:

details of the current number and severity of exacerbations compared to baseline levels provided in the initial authority application of this treatment cycle including:

(i) number of moderate exacerbations requiring treatment with systemic corticosteroids; and/or

(ii) number of moderate exacerbations requiring treatment with antibiotics; and

(iii) number of severe exacerbation(s) which required hospitalisation.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

Uncontrolled chronic obstructive pulmonary disease (COPD)

Treatment Phase: Grandfather arrangements - Transitioning from non-PBS to PBS-subsidised supply

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 September 2026, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre in the 12 months prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have achieved, prior to commencing non-PBS-subsidised treatment with this drug for this condition, adequate control with at least 3 months of optimised triple inhaled therapy consisting of: (i) long-acting muscarinic antagonist (LAMA); (ii) a long-acting beta-2 agonist (LABA); (iii) an inhaled corticosteroid (ICS), despite formal assessment of and adherence to correct inhaler technique which has been documented in the patient's medical records, **AND**
- Patient must have experienced at least one severe COPD exacerbation, or at least two moderate COPD exacerbations in the 12 months prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with all of: (i) LAMA; (ii) LABA; (iii) ICS in an optimised triple inhaler therapy, **AND**
- Patient must have both, achieved and sustained an adequate response to this drug, defined as maintenance (i.e. no change); or a reduction in the number of moderate and/or severe exacerbation(s) compared to the baseline levels provided with this authority application, if they received at least 24 weeks of treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician; (ii) general physician experienced in the management of patients with this condition.

For the purpose of administering this restriction, COPD exacerbations in the 12 months prior to commencing non-PBS-subsidised treatment with this drug for this condition, are defined as experiencing:

(i) at least 1 severe COPD exacerbation which required hospitalisation; and/or

(ii) 2 or more moderate COPD exacerbations, of which at least:

(a) one required treatment with systemic corticosteroids; and

(b) one required treatment with systemic corticosteroids or antibiotics.

At least one of the moderate or severe exacerbations must have occurred while the patient was taking all of: (i) LAMA; (ii) LABA; and (iii) ICS in an optimised triple inhaler therapy.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include the following:

(i) the blood eosinophil count and date; AND

(ii) details of therapy with a combination of LAMA, LABA and ICS (name of treatment, dosage, date of commencement, and duration of therapy prior to commencing non-PBS-subsidised treatment with this drug for this condition); AND

(iii) the baseline exacerbation history which includes:

details of the number and severity of COPD exacerbations experienced in the 12 months immediately prior to commencement of this drug as non-PBS-subsidised therapy for this condition, including:

(a) number of moderate exacerbations requiring treatment with systemic corticosteroids; and/or

(b) number of moderate exacerbations requiring treatment with antibiotics; and

(c) number of severe exacerbations requiring hospitalisation; AND

(iv) the assessment of response to treatment where applicable (for patients who have received at least 24 weeks of treatment), which includes:

details of the current number and severity of COPD exacerbations, compared with the baseline information supplied in this authority application, including:

(a) number of moderate exacerbations requiring treatment with systemic corticosteroids; and/or

(b) number of moderate exacerbations requiring treatment with antibiotics; and

(c) number of severe exacerbations requiring hospitalisation.

The details of the number and the severity of COPD exacerbations are to inform the basis of determining if an adequate response to treatment has been achieved under the continuing treatment restriction.

In addition to stating the above details in the authority application, document them in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

mepolizumab 100 mg/mL injection, 1 mL pen device

15511J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1556.10	Nucala [GK]

MIDOSTAURIN

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

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

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

Acute Myeloid Leukaemia

Treatment Phase: Maintenance therapy - Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial maintenance treatment restriction, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

A maximum of 9 cycles will be authorised under this restriction in a lifetime.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;

- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

midostaurin 25 mg capsule, 112

11505M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	2	0.00	18422.74	Rydapt [NV]

MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

19485

Prophylaxis of renal allograft rejection

Treatment Phase: Management

Clinical criteria:

- The treatment must be under the supervision and direction of a transplant unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Note Management includes initiation, stabilisation and review of therapy as required.

mycophenolate 180 mg enteric tablet, 120

15681H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*141.88	[a] Mycophenolic Acid ARX [XT]	[a] Myfortic [NV]

mycophenolate 360 mg enteric tablet, 120

15651R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*261.14	[a] Mycophenolic Acid ARX [XT]	[a] MYCOTEX [CR]
					[a] Myfortic [NV]	

MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

19365

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19366

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

mycophenolate mofetil 250 mg capsule, 100

9501C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	5	0.00	*115.20	[a] APO-Mycophenolate [TX]	[a] Mycophenolate Sandoz [SZ]

9501C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
					[a] Pharmacor Mycophenolate 250 [CR]	

mycophenolate mofetil 500 mg tablet, 50

9502D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	5	0.00	*115.08	[a] ARX-MYCOPHENOLATE [XT]	[a] Ceptolate [AF]
					[a] Mycophenolate GH [GQ]	[a] Mycophenolate Sandoz [SZ]
					[a] Pharmacor Mycophenolate 500 [CR]	

mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL

9500B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*372.20	[a] CellCept [RO]	[a] Pharmacor Mycophenolate [CR]

OCTREOTIDE

Authority Required (STREAMLINED)

19539

Functional carcinoid tumour

Clinical criteria:

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Treatment criteria:

- Must be treated by a medical practitioner where the prescription continues existing therapy with this medicine; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority Required (STREAMLINED)

19549

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Treatment criteria:

- Must be treated by a medical practitioner where the prescription continues existing therapy with this medicine; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

15627L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*789.16	Sandostatin LAR [NV]

octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

15658D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*1050.62	Sandostatin LAR [NV]

octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

15647M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*1207.32	Sandostatin LAR [NV]

OCTREOTIDE

Authority Required (STREAMLINED)

19322

Functional carcinoid tumour

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**

- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority Required (STREAMLINED)

19479

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 50 microgram/mL injection, 5 x 1 mL ampoules

15670R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	18	11	0.00	*252.00	[a] Octreotide GH [HQ]	[a] Octreotide (SUN) [RA]
					[a] Sandostatin 0.05 [NV]	

octreotide 100 microgram/mL injection, 5 x 1 mL ampoules

15638C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	18	11	0.00	*504.00	[a] Octreotide GH [HQ]	[a] Octreotide (SUN) [RA]
					[a] Sandostatin 0.1 [NV]	

octreotide 500 microgram/mL injection, 5 x 1 mL ampoules

15672W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	18	11	0.00	*1870.38	[a] Octreotide GH [HQ]	[a] Octreotide (SUN) [RA]
					[a] Sandostatin 0.5 [NV]	

OCTREOTIDE

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

Authority Required (STREAMLINED)

19562

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

Clinical criteria:

- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be either: (i) as monotherapy; (ii) in combination with cabozantinib.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a medical practitioner where the prescription continues existing therapy with this medicine; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

11893Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*1207.32	Sandostatin LAR [NV]

ONASEMNOGENE ABEPARVOVEC

Note Other disease modifying therapies for this condition are: (i) nusinersen, (ii) risdiplam.

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Note Accredited treatment centres and suppliers are those organisations accredited by the Gene Technology Regulator under section 92 of the *Gene Technology Act 2000*.

The following website provides a list of accredited organisations and may update without notice:

https://www.ogtr.gov.au/what-weve-approved/accredited-organisations

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Spinal muscular atrophy (SMA)

Treatment Phase: Use in a patient untreated with disease modifying therapies for this condition

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age; **OR**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes, **AND**
- The treatment must be given concomitantly with best supportive care for this condition.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime, **AND**
- Patient must not be undergoing treatment with this pharmaceutical benefit through this listing where prior treatment has occurred with any of: (i) nusinersen, (ii) risdiplam.

Population criteria:

- Patient must weigh 21 kg or less
- Patient must have symptomatic Type I, II or IIIa SMA; **OR**
- Patient must have pre-symptomatic SMA with 1-2 copies of the SMN2 gene and are no older than 36 months of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

In the relevant PBS Authority Application form, specify the following:

(i) the SMA type being treated: symptomatic Type I, II or IIIa SMA, or, pre-symptomatic SMA;

(ii) for Type I, II or IIIa SMA, the signs/symptoms that the patient has experienced, together with the patient's age at the onset of these signs/symptoms.

State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.

Confirm that genetic testing has been completed to demonstrate the following in support of an SMA diagnosis:

(i) 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or

(ii) deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variance in the remaining single copy of the SMN1 gene.

If the condition is pre-symptomatic SMA, confirm that there is genetic test finding that substantiates the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA).

Quote the date, pathology provider name and any unique identifying serial number/code that links the genetic test result to the patient.

Defined signs and symptoms of type I SMA are:

i) Onset before 6 months of age; and

ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or

iii) Proximal weakness; or

iv) Hypotonia; or

v) Absence of deep tendon reflexes; or

vi) Failure to gain weight appropriate for age; or

vii) Any active chronic neurogenic changes; or

viii) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

i) Onset between 6 and 18 months; and

ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or

iii) Proximal weakness; or

iv) Weakness in trunk righting/derotation; or

v) Hypotonia; or

vi) Absence of deep tendon reflexes; or

vii) Failure to gain weight appropriate for age; or

viii) Any active chronic neurogenic changes; or

ix) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type IIIa SMA are:

i) Onset between 18 months and 3 years of age; and

ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or

iii) Proximal weakness; or

iv) Hypotonia; or

v) Absence of deep tendon reflexes; or

vi) Failure to gain weight appropriate for age; or

vii) Any active chronic neurogenic changes; or

viii) A compound muscle action potential below normative values for an age-matched child.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Authority Required

Spinal muscular atrophy (SMA)

Treatment Phase: Use occurring after treatment with at least one disease modifying therapy for this condition (i.e. switching from nusinersen/risdiplam to onasemnogene abeparvovec)

Clinical criteria:

- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes.

Treatment criteria:

- Patient must be undergoing treatment with this pharmaceutical benefit following prior PBS-subsidised treatment with at least one other disease modifying therapy for this condition, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit with the intent that treatment with the replaced disease modifying agent is/has ceased.

Population criteria:

- Patient must weigh 21 kg or less

- Patient must have symptomatic Type I, II or IIIa SMA; **OR**
- Patient must have pre-symptomatic SMA with 1-2 copies of SMN2 gene where a disease-modifying therapy (DMT) was initiated prior to 36 months of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.

Confirm that a previous PBS authority application has been approved for one of the following:

(i) Symptomatic Type I, II or IIIa SMA; or

(ii) Pre-symptomatic SMA with 1-2 copies of SMN2 gene.

State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.

Adhere to any Product Information or local treatment guidelines with respect to treatment-free ('wash out') periods prior to administering this benefit.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack

12951P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack

12977B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack

12942E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack

12976Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack

12975X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack

12956X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8 x 8.3 mL vials], 1 pack

12964H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [9 x 8.3 mL vials], 1 pack

15594R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [10 x 8.3 mL vials], 1 pack

15600C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [11 x 8.3 mL vials], 1 pack

15595T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [12 x 8.3 mL vials], 1 pack

15596W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [13 x 8.3 mL vials], 1 pack

15589L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8.3 mL vial], 1 pack

12955W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack

12958B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack

12940C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack

12950N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack

12963G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack

12941D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack

12952Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8 x 8.3 mL vials], 1 pack

15580B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [9 x 8.3 mL vials], 1 pack

15544D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [10 x 8.3 mL vials], 1 pack

15562C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [11 x 8.3 mL vials], 1 pack

15581C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [12 x 8.3 mL vials], 1 pack

15579Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 2 x 8.3 mL vials

12957Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 3 x 8.3 mL vials

12961E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 4 x 8.3 mL vials

12971Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 5 x 8.3 mL vials

12962F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 6 x 8.3 mL vials

12973T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 7 x 8.3 mL vials

12954T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 8 x 8.3 mL vials

12974W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 9 x 8.3 mL vials

12949M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 10 x 8.3 mL vials

15554P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 11 x 8.3 mL vials

15588K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 12 x 8.3 mL vials

15602E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 13 x 8.3 mL vials

15578X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 14 x 8.3 mL vials

15545E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

ONASEMNOGENE ABEPARVOVEC

Note Other disease modifying therapies for this condition are: (i) nusinersen, (ii) risdiplam.

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Note Accredited treatment centres and suppliers are those organisations accredited by the Gene Technology Regulator under section 92 of the *Gene Technology Act 2000*.

The following website provides a list of accredited organisations and may update without notice:

https://www.ogtr.gov.au/what-weve-approved/accredited-organisations

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Spinal muscular atrophy (SMA)

Treatment Phase: Use in a patient untreated with disease modifying therapies for this condition

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes, **AND**
- The treatment must be given concomitantly with best supportive care for this condition.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime, **AND**
- Patient must not be undergoing treatment with this pharmaceutical benefit through this listing where prior treatment has occurred with any of: (i) nusinersen, (ii) risdiplam.

Population criteria:

- Patient must weigh 21 kg or less
- Patient must be under 36 months of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.

Confirm that genetic testing has been completed to demonstrate the following in support of an SMA diagnosis:

(i) 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or

(ii) deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variance in the remaining single copy of the SMN1 gene.

Confirm that there is a genetic test finding that substantiates the number of SMN2 gene copies to be 3 and has been determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA).

Quote the date, pathology provider name and any unique identifying serial number/code that links the genetic test result to the patient.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Authority Required

Spinal muscular atrophy (SMA)

Treatment Phase: Use occurring after treatment with at least one disease modifying therapy for this condition (i.e. switching from nusinersen/risdiplam to onasemnogene abeparvovec)

Clinical criteria:

- The treatment must be given concomitantly with best supportive care for this condition, **AND**

- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes.

Treatment criteria:

- Patient must be undergoing treatment with this pharmaceutical benefit following prior PBS-subsidised treatment with at least one other disease modifying therapy for this condition prior to 36 months of age, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit with the intent that treatment with the replaced disease modifying agent is/has ceased.

Population criteria:

- Patient must weigh 21 kg or less
- Patient must have pre-symptomatic SMA with 3 copies of the SMN2 gene.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.

Confirm that a previous PBS authority application has been approved for pre-symptomatic SMA with 3 copies of SMN2 gene.

State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.

Adhere to any Product Information or local treatment guidelines with respect to treatment-free ('wash out') periods prior to administering this benefit.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack

13671M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack

13670L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack

13672N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack

13680B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack

13677W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack

13662C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8 x 8.3 mL vials], 1 pack

13666G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [9 x 8.3 mL vials], 1 pack

15559X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [10 x 8.3 mL vials], 1 pack

15570L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [11 x 8.3 mL vials], 1 pack

15586H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [12 x 8.3 mL vials], 1 pack

15561B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [13 x 8.3 mL vials], 1 pack

15582D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8.3 mL vial], 1 pack

13663D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack

13669K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack

13682D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack

13683E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack

13681C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack

13679Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack

13668J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8 x 8.3 mL vials], 1 pack

15551L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [9 x 8.3 mL vials], 1 pack

15547G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [10 x 8.3 mL vials], 1 pack

15598Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [11 x 8.3 mL vials], 1 pack

15546F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [12 x 8.3 mL vials], 1 pack

15587J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 2 x 8.3 mL vials

13674Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 3 x 8.3 mL vials

13678X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 4 x 8.3 mL vials

13665F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 5 x 8.3 mL vials

13667H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 6 x 8.3 mL vials

13664E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 7 x 8.3 mL vials

13675R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 8 x 8.3 mL vials

13673P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 9 x 8.3 mL vials

13676T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 10 x 8.3 mL vials

15552M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 11 x 8.3 mL vials

15577W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 12 x 8.3 mL vials

15601D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 13 x 8.3 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15604G	‡1	0	0.00	2527773.87	Zolgensma [NV]

Onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 14 x 8.3 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15553N	‡1	0	0.00	2527773.87	Zolgensma [NV]

PEGFILGRASTIM

Authority Required (STREAMLINED)

19332

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19403

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
9514R NP	1	11	0.00	77.52	[a] Pelgraz [OC]	[a] Ziextenzo [SZ]

SIROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

19365

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

sirolimus 500 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9747B NP	2	5	0.00	*587.54	Rapamune [PF]

sirolimus 1 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9549N NP	2	5	0.00	*1175.04	Rapamune [PF]

sirolimus 1 mg/mL oral liquid, 60 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9550P NP	2	5	0.00	*924.02	Rapamune [PF]

sirolimus 2 mg tablet, 100

9548M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*2350.12	Rapamune [PF]

TACROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

19315

Management of rejection in patients following organ or tissue transplantation

Clinical criteria:

- The treatment must be under the supervision and direction of a transplant unit, **AND**
- The treatment must include initiation, stabilisation, and review of therapy as required.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

tacrolimus 500 microgram capsule, 100

9558C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*108.00	[a] Pacrolim [AF]	[a] Pharmacor Tacrolimus 0.5 [CR]
					[a] Prograf [LL]	[a] Tacrograf [RW]
					[a] Tacrolimus Sandoz [SZ]	

tacrolimus 500 microgram modified release capsule, 30

9664P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*75.04	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 750 microgram capsule, 100

10859M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*164.14	Tacrolimus Sandoz [SZ]

tacrolimus 1 mg capsule, 100

9560E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*214.00	[a] Pacrolim [AF]	[a] Pharmacor Tacrolimus 1 [CR]
					[a] Prograf [LL]	[a] Tacrograf [RW]
					[a] Tacrolimus Sandoz [SZ]	

tacrolimus 1 mg modified release capsule, 60

9665Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*126.00	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 2 mg capsule, 100

10860N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*469.30	Tacrolimus Sandoz [SZ]

tacrolimus 3 mg modified release capsule, 50

11907Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	0.00	*689.00	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 5 mg capsule, 50

9561F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*524.86	[a] Pharmacor Tacrolimus 5 [CR]	[a] Prograf [LL]
					[a] Tacrograf [RW]	[a] Tacrolimus Sandoz [SZ]

tacrolimus 5 mg modified release capsule, 30

9666R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*780.00	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

TEPROTUMUMAB

Caution Teprotumumab is contraindicated in pregnancy. Women of childbearing potential should have a negative pregnancy test before starting treatment with teprotumumab, and monthly during treatment and for 6 months after cessation of treatment. If the patient becomes pregnant during treatment, teprotumumab should be discontinued. See also TGA approved Product Information.

Caution Assess patient's hearing before, and routinely during and after treatment, including use of audiograms where clinically warranted.

If significant hearing loss is experienced while receiving treatment with this drug for this condition, treatment discontinuation is advised. See also TGA approved Product Information.

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

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

19524

Active moderate to severe thyroid eye disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the management of thyroid eye disease; or in consultation with a specialist medical practitioner experienced in the management of thyroid eye disease.

Increased quantities may only be authorised where a patient's weight is greater than 150 kg.

After completing 8 doses in total of PBS-subsidised treatment with teprotumumab, a patient may be eligible for re-treatment through the initial treatment phase only, if a response to treatment was previously demonstrated.

Teprotumumab 500 mg injection, 1 vial

15593Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6	6	0.00	*63886.08	Tepezza [AN]

TEPROTUMUMAB

Caution Teprotumumab is contraindicated in pregnancy. Women of childbearing potential should have a negative pregnancy test before starting treatment with teprotumumab, and monthly during treatment and for 6 months after cessation of treatment. If the patient becomes pregnant during treatment, teprotumumab should be discontinued. See also TGA approved Product Information.

Caution Assess patient's hearing before, and routinely during and after treatment, including use of audiograms where clinically warranted.
If significant hearing loss is experienced while receiving treatment with this drug for this condition, treatment discontinuation is advised. See also TGA approved Product Information.

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

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

Note Special Pricing Arrangements apply.

Authority Required

Active moderate to severe thyroid eye disease

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be both: (i) undergoing re-treatment with this drug for this condition; and (ii) have demonstrated response to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a clinical activity score (CAS) of at least three for the most severely affected eye, **AND**
- Patient must have two or more of the following: (i) Proptosis at least 3 mm above normal for race and gender; (ii) Lid retraction of at least 2 mm; (iii) Moderate to severe soft-tissue involvement; (iv) Inconstant or constant diplopia.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the treatment of thyroid eye disease.

The following must be provided at the time of application and documented in the patient's medical records for the first prescription only:

(1) Baseline clinical activity score (CAS); and

(2) Confirmation of the presence of thyroid eye disease.

This includes evidence of two or more of the following:

(i) Proptosis at least 3 mm above normal for race and gender;

(ii) Lid retraction of at least 2 mm;

(iii) Moderate to severe soft-tissue involvement;

(iv) Inconstant or constant diplopia.

Increased quantities may only be authorised where a patient's weight is greater than 150 kg.

After completing 8 doses in total of PBS-subsidised treatment with teprotumumab, a patient may be eligible for re-treatment through the initial treatment phase only, if a response to treatment was previously demonstrated.

Teprotumumab 500 mg injection, 1 vial

15569K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	0	0.00	*31943.04	Tepezza [AN]

TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be at least 12 years of age.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56

15655Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	18952.50	Symdeko [VR]

TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority Required

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist respiratory physician with expertise in cystic fibrosis, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be at least 12 years of age.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56

15667N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	18952.50	Symdeko [VR]

NP

VALGANCICLOVIR

Authority Required (STREAMLINED)

19374

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Authority Required (STREAMLINED)

19515

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

valganciclovir 50 mg/mL powder for oral liquid, 100 mL

9655E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	11	5	0.00	*4346.10	Valcyte [PB]

valganciclovir 450 mg tablet, 60

9569P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*476.22	[a] Valganciclovir Sandoz [SZ]	[a] Valganciclovir Viatris [AL]

ZOLEDRONIC ACID

Authority Required (STREAMLINED)

19428

Adjuvant management of breast cancer

Population criteria:

- Patient must be post-menopausal.

Treatment criteria:

- Patient must not be undergoing PBS-subsidised treatment with this drug for this indication for more than 36 months, **AND**
- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

zoledronic acid 4 mg/5 mL injection, 5 mL vial

13773X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	0	0.00	45.72	[a] DEZTRON [DZ]	[a] Zoledronate-DRLA 4 [RZ]
					[a] Zoledronic Acid Accord [OC]	

Highly Specialised Drugs Program (Community Access)

CLOZAPINE

Authority Required (STREAMLINED)

19507

Schizophrenia

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a psychiatrist; **OR**
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with the treating psychiatrist, (ii) the prescription continues existing therapy with this medicine.

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have completed at least 18 weeks therapy, **AND**
- Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**
- The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Pfizer ClopineCentral.

clozapine 50 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11422E NP	‡1	0	0.00	155.68	25.00	Versacloz [DU]

CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed.

Authority Required (STREAMLINED)

19429

Schizophrenia

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a psychiatrist; **OR**
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with the treating psychiatrist, (ii) the prescription continues existing therapy with this medicine.

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have completed at least 18 weeks therapy, **AND**
- Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**
- The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 200 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10288L NP	2	0	0.00	*460.66	25.00	Clopine 200 [DU]	Clozitor [JU]

CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed.

Authority Required (STREAMLINED)

19469

Schizophrenia

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a psychiatrist; **OR**
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with the treating psychiatrist, (ii) the prescription continues existing therapy with this medicine.

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have completed at least 18 weeks therapy, **AND**
- Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**
- The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 25 mg tablet, 100

10289M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	0	0.00	*71.12	25.00	Clopine 25 [DU] Clozitor [JU]	Clozaril 25 [GO]

NP

CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed.

Authority Required (STREAMLINED)

19290

Schizophrenia

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a psychiatrist; **OR**
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with the treating psychiatrist, (ii) the prescription continues existing therapy with this medicine.

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have completed at least 18 weeks therapy, **AND**
- Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**
- The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 50 mg tablet, 100

10302F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	0	0.00	*129.64	25.00	Clopine 50 [DU]	Clozitor [JU]

NP

CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed.

Authority Required (STREAMLINED)

19470

Schizophrenia

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a psychiatrist; **OR**
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with the treating psychiatrist, (ii) the prescription continues existing therapy with this medicine.

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have completed at least 18 weeks therapy, **AND**
- Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**

- The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 50 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10341G NP	1	0	0.00	155.68	25.00	Clopine Suspension [DU]

CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed.

Authority Required (STREAMLINED)

19467

Schizophrenia

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a psychiatrist; **OR**
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with the treating psychiatrist, (ii) the prescription continues existing therapy with this medicine.

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have completed at least 18 weeks therapy, **AND**
- Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**
- The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10358E NP	2	0	0.00	*234.94	25.00	Clopine 100 [DU] Clozitor [JU]	Clozaril 100 [GO]

LANREOTIDE

Note Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Authority Required (STREAMLINED)

19548

Functional carcinoid tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
15668P NP	2	5	0.00	*1821.78	25.00	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
15636Y NP	2	5	0.00	*2402.22	25.00	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
15679F NP	2	5	0.00	*2728.40	25.00	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

LANREOTIDE

Note Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

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

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

Authority Required (STREAMLINED)

19547

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be either: (i) as monotherapy; (ii) in combination with cabozantinib.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

15619C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*2728.40	25.00	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

OCTREOTIDE

Authority Required (STREAMLINED)

19540

Functional carcinoid tumour

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Treatment criteria:

- Must be treated by a medical practitioner where the prescription continues existing therapy with this medicine; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority Required (STREAMLINED)

19533

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Treatment criteria:

- Must be treated by a medical practitioner where the prescription continues existing therapy with this medicine; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

15609M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	0.00	*865.26	25.00	Sandostatin LAR [NV]

octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

15659E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	0.00	*1145.04	25.00	Sandostatin LAR [NV]

octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

15669Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	0.00	*1308.48	25.00	Sandostatin LAR [NV]

OCTREOTIDE

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

Authority Required (STREAMLINED)

19565

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be either: (i) as monotherapy; (ii) in combination with cabozantinib.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a medical practitioner where the prescription continues existing therapy with this medicine; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a specialist medical practitioner, (ii) the prescription continues existing therapy with this medicine.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

11896D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	0.00	*1308.48	25.00	Sandostatin LAR [NV]

Botulinum Toxin Program

INCOBOTULINUMTOXINA

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

19313

Moderate to severe spasticity of the lower limb following an acute event

Clinical criteria:

- The condition must be moderate to severe spasticity of the lower limb/s following stroke or other acute neurological event, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must only be used as second line therapy when standard management has failed; **OR**
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating of at least 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A), **AND**
- Patient must not have established severe contracture in the limb to be treated, **AND**
- The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per lower limb in the the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per lower limb each year thereafter.

Treatment criteria:

- Must be treated by a neurologist; **OR**
- Must be treated by an orthopaedic surgeon; **OR**
- Must be treated by a rehabilitation specialist; **OR**
- Must be treated by a plastic surgeon; **OR**
- Must be treated by a geriatrician.

Population criteria:

- Patient must be at least 18 years of age.

Standard management includes physiotherapy and/or oral spasticity agents.

Note An acute event may be a clinical or external event that leads to upper motor neuron lesions resulting in spasticity for example stroke, traumatic brain injury, spinal cord injury, infection or hypoxia.

incobotulinumtoxinA 100 units injection, 1 vial

15574Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	0	0.00	*1320.04	25.00	Xeomin [EJ]